

THE GMP FACILITY FOR THE PRODUCTION OF BIOPHARMACEUTICALS AND VECTORS

Operates as a part of the Goldyne Savad Institute of Gene Therapy

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Objectives:

The main objective of this Facility is the production of vectors and cells for use in human clinical trials, primarily vectors for use in Phase I/II of the trials. The facility is the stage which mediates between the researcher/scientist and the application of research ideas for the treatment of specific diseases in patients. The purpose of work at the facility is to produce materials (therapeutic agents) under conditions that are acceptable to the American FDA.

Usually, research starts with an idea; the idea is tested in the research laboratory (in vitro assays) then on laboratory animals (in vivo assays). The final stage after researchers are convinced that the potential therapy is effective, is the clinical trials stage. At this stage the potential therapeutic agent is produced under GMP (Good Manufacturing Practices) conditions and given to a group of patients. The GMP conditions have been defined by the American FDA. These are the optimal conditions for reproducible and aseptic production of medicines. In order to achieve these conditions the Vector Production Facility was built.



Work according to GMP regulations



Work according to SOPs ensuring aseptic techniques

Structure:

The facility occupies about 300 m² and contains 4 operational class 10,000 laboratories.

The facility consists of two functionally and physically separate areas: 1. A “gray” area, which includes a storage room, offices, a Quality Control (QC) lab outfitted with cell culture and molecular biology equipment, and a chemical fume hood. Adjacent to the QC there is a room for low temperature (-80°C) freezers. 2. A “white” area, with four separate production laboratories and common supportive facilities. The “gray” and “white” areas are separated by an air lock vestibule with interlocked double doors, which serves as a gowning room. In order to prevent cross-contamination, access to each one of the production modules is through additional interlocked double door vestibules, which serve for degowning and re-gowning before entering or leaving each of the production areas. Air supply to the different zones is controlled by separate air handling units. Air is supplied through highly efficient particulate air (HEPA) filters, under positive pressure. The HEPA filters provide class 100,000 and class 10,000 environments to the different rooms of the controlled area. For containment purposes, positive air pressure, relative to the adjacent production modules, is maintained in the air lock vestibules.



Seamless walls and pass-through windows

SIZE µm	DIFF N/CU-FT	ACCUM N/CU-FT
0.3	3781.0	4324.0
0.5	340.0	543.0
0.7	110.0	203.0
1.0	54.0	93.0
2.0	18.0	39.0
3.0	11.0	21.0
5.0	3.0	10.0
10.0	7.0	7.0

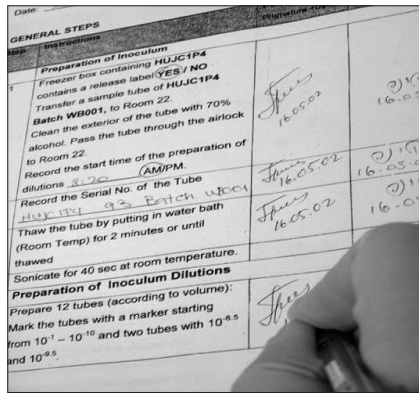
FLOW: 1.0 CFM LREF: 8.1 U OK

Total particles monitoring

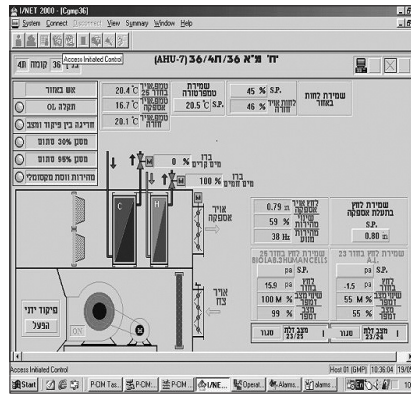
Compliance with GMP regulations:

The facility operates in compliance with current GMP (cGMP) requirements:

1. The physical structure of the facility fits the requirements.
2. The air is filtered to a defined particle level per square foot.
3. Environmental monitoring of total particles and number of viable particles per square foot is performed daily.
4. Work proceeds only according to SOP's and is fully recorded.



SOP's for the performance of all work with double signatures



Computerized monitoring program

Access to the facility is limited to authorized personnel who may enter by activating an electrical door by a personal magnetic card.

A computerized alert program monitors the rooms and major pieces of equipment located in them, for deviations in temperature, humidity, vacuum, and CO₂ content. The equipment is calibrated periodically and maintained according to GMP requirements.