



Hadassah
University
Hospital



Clinical Research Ward staff:

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Cohen Meital, Medical Secretary

Which previous projects were performed at the GMP?

Private companies and research groups from Hadassah produced various biological products for clinical trials as follows:

- ◆ Production of radioactive antibodies for the treatment of melanoma patients (PTI, U.S.)
- ◆ Genetic engineering of skin tissues (Medgenics, Israel)
- ◆ Viral vector production (MGVS, Israel)
- ◆ Mesenchymal stem cell production, a collaborative project between Hadassah and Teva Pharmaceuticals, Israel
- ◆ Oncolytic virus production (OVCure, Israel)
- ◆ Amplification of cord blood stem cells (Gamida Cell, Israel)
- ◆ Production of tumor antigen-loaded dendritic cells (Hadassah, Israel)
- ◆ Cellular immunization production for the treatment of multiple sclerosis (Hadassah, Israel)
- ◆ Production of coated sponges for wound treatment (Hapto, Israel)
- ◆ Production of embryonic stem cells (Hadassa, Israel)

Course for clean room technology

This course is taught by Dr. Linda Rasooly and Dr. Mordechai Izhar, in a joint collaboration between The Gene Therapy Institute and Bioforum. It is designed for production managers, quality control managers, heads of research groups and GMP maintenance personnel from pharmaceutical industries and biotechnological companies.

The course program focuses on rules and working methods in clean rooms, according to FDA regulations followed by on site demonstrations.

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The GMP Laboratory

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The GMP Laboratory

Laboratory for the production of pharmaceuticals and vectors

The Goldyne Savad Institute
of Gene Therapy
Hadassah Medical Organization
Hadassah Hebrew University Hospital

All facilities within Hadassah University Hospital Campus:

- GMP Facility
- Hospital's Labs
- Hospital's Clinical Ward
- P3 Labs
- The Hebrew University's Faculty of Medicine
- Jerusalem BioPark



What is the GMP Laboratory?

The GMP (Good Manufacturing Practice) laboratory is an FDA-compliant manufacturing facility for the production of pharmaceutical products under aseptic conditions, mainly for clinical trials.

What is the objective of the GMP facility at Hadassah?

The GMP facility at Hadassah provides the opportunity to establish collaborative networks and accelerate the development of clinical trials for the treatment of human diseases. It is structured to attract and facilitate translational research to the clinic and receive all the benefits inherent in a leading university hospital. The GMP facility and staff are easily accessible and accompany the project through all phases of development, starting with the initial research stage at the Gene Therapy Institute's laboratory, through production at the GMP facility, and finally to clinical trial at the Institute's Clinical Research Ward. With the establishment of the new Biotechnology Research Park within the Hadassah complex, companies can rent laboratory and office space, thus creating a unique opportunity for the investigator to personally be involved in all phases of development from production at the GMP facility to clinical trial.

What kind of products can be produced?

The GMP facility is designed for the production of biological, medicinal and chemical products, as follows:

- ◆ Cell cultures
- ◆ Tissues
- ◆ Viruses
- ◆ Bacteria
- ◆ Molecules for use in clinical trials, antibodies bound to radioactive atoms for cancer treatment

What are the GMP standards of performance?

- ◆ The GMP facility at Hadassah functions according to FDA regulations with regard to production of biological and chemical products in clean rooms. Recently, the FDA has approved a drug originating from our GMP facility for use in patient clinical trial in the U.S.
- ◆ The GMP facility conforms to the Standards Institution of Israel.
- ◆ The facility complies with the European Medicines Agency (EMA)'s standards, the EC regulatory agency.

According to which cleaning standards do we operate?

The clean rooms classified as class 10,000 and the laminar flow hood as class 100.

How is the facility structured?

- ◆ The clean zone is composed of 4 clean rooms, equipped with biological hoods, incubators and centrifuges.
- ◆ The clean rooms are adjusted to serve different types of projects. Researchers are permitted to bring their own equipment to perform their projects.
- ◆ Support zone: Composed of freezers, autoclaves, PCR, ELISA reader and a quality control room.
- ◆ In the laboratory infrastructure complex large funds have been invested to build the highest quality

construction. The rooms were built from special materials fabricated by Steril, an Italian company with expertise in clean rooms construction.

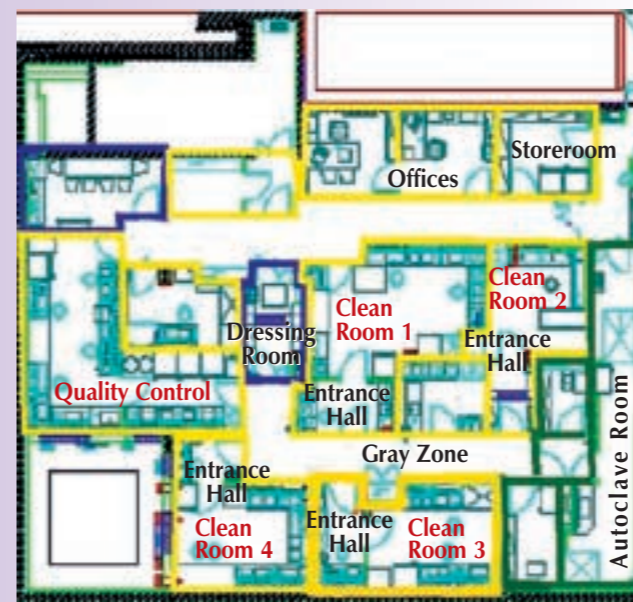
- ◆ Particle levels are continuously checked and monitored on a daily basis.

How is the cleanliness checked?

At the end of each work day, air and work surfaces are tested to prevent microbiological contamination.

How is quality control supervised?

- ◆ The air is monitored for the total particles as well as viable ones.
- ◆ A computerized control system monitors equipment and systems 24 hr/day. An alarm system alerts workers in case of malfunction; the staff is available 24/hr day to repair any malfunction.
- ◆ A system for air pressure regulation between rooms is also monitored.
- ◆ Access to facility is restricted to authorized personnel only.



Who is our staff?



Linda Rasooly, Ph.D. (Microbiology)
Head of the GMP Laboratory since 2001.

Certified in clean room technology according to FDA regulations and quality control assurance and accredited in the following courses:

- ◆ **Performing internal quality audits** - The Standards Institution of Israel
- ◆ **Clean room management** - Forum Training and Enrichment, Israel
- ◆ **US FDA regulatory compliance** - The Center for Professional Advancement, The Netherlands
- ◆ **Advanced methods for industrial production, purification and characterization of gene vectors** - Genethon, France
- ◆ **Current issues in quality and manufacturing of biotechnology products** - BioForum, Israel
- ◆ **GMP and FDA compliant quality and documentation systems** - European compliance Academy, Denmark

Our GMP staff is highly skilled, fully trained and ready to be at your service:

Orit Daniel, B.Sc., Medical Technician

Bizalel Dikla, B.Sc., Medical Technician

Yelena Vahnin, Ph.D. in Technical Sciences, Technical Maintenance and Monitoring Engineer

Tarek Hatib – Maintenance

Investigators are welcome to bring their own personnel to be trained by Dr. Rasooly on working procedures at the GMP facility.