MANAK

Cleanroom Technology

CLEANROOM
Design & Construction

MACHINERY
Supply & Installing

GMP
Training & Consulting

New
Collections

BIULT TO LAST ...

Design and Construction of Cleanroom
Supplying of Pharmaceutical Machinery

www.manakpharmed.com

MANAK
Cleanroom Technology

Company Profile

Manak Pharmed is a Leading Company in clean room design and Construction in GMP related industries.

Manak Pharmed efforts in the field of design, engineering, implementation and validation of clean rooms for pharmaceutical, hospitals, cosmetics and food industries.

The company has developed a unique expertise in the design and implementation of controlled and clean environments by a team with more than 15 years of experience. Manak has a global approach, serving clients who are technically aspiring to operate in markets such as pharmaceuticals, food, cosmetics and biopharma. The company offers a full range of services from consulting to managing turnkey solutions, delivered with the highest quality and safety standards.

VISION

To be an integrated player in Cleanroom Solutions offering world class products and services to customers according to recent standards and requirements.

MISSION

To focus on delivering great value to customers through highly skilled professionals delivering world class Projects and Products.

What is **Cleanroom**?

A cleanroom is: room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary.

More accurately, a cleanroom has a controlled level of contamination that is specified by the number of particles per cubic meter at a specified particle size. In addition, the temperature and humidity is also controlled.

Grade	Maximum limits for total particle ≥ 0.5 µm/m³		Maximum limits for total particle ≥ 5 µm/m³	
	At Rest	**in Operation**	**At Rest**	**in Operation**
A	3 520	3 520	Not specified [a]	Not specified [a]
B	3 520	352 000	Not specified [a]	2 930
C	352 000	3 520 000	2 930	29 300
D	3 520 000	Not predetermined [b]	29 300	Not predetermined [b]

Industries we serve

Manak offers a total cleanroom solution from conception to completion

All our architectural elements for clean rooms, designed and manufactured in our production center are designed to offer a hygienic finish and comply with the different regulations such as GMP rules. GMP Modular or conventional cleanroom partitioning system is designed for ease in installation and practical functionality, while maintaining a modular flexibility. Simplified construction methods and progressive & non- progressive systems help our client's to minimize overall construction time.

Our product line

- **Pre-engineered powder-coated modular panels**
- **Pre-painted modular panels**
- **GRP (Glass Reinforced Polymer) modular panels**
- **HPL (High Pressure Laminate) modular panels**
- **Cleanroom Metal Doors**
- **Fire Rated Metal Doors**

Pharmaceuticals

- Injectable
- Oncology & Hazard
- OSD
- LVP/ SVP
- Oral Solution
- API
- Biotechnology
- R & D Lab

Other Industries:

- Medical devices
- Veterinary
- Hospital
- Food and beverages
- Semiconductor
- Solar panels
- Electronics
- Glass manufacturing

Advantage – Manak Solutions

Why Manak Pharmed

- Team having a rich pharmaceutical experience
- Familiar with recent GMP Principles
- Ability of understand customer's requirements
- State of the art products and services
- Manufacturing facilities at two strategic locations in Iran for; fast production and delivery
- Representative of STP China
- Own installation team ensuring timely project completion
- Products in compliance with the regulatory requirements
- Latest updated technology as per current industrial needs

Clean Room Design & Construction

Our team of industry experts specialize in cleanroom consultation, design, engineering, and the construction of turnkey cleanroom installations across all industries that require controlled environments. When you work with MANAK PHARMED you are guaranteed the most state of the art technology and the highest quality of specialized engineering for your cleanroom project.

EU GMP

ISPE

ISO

14644-1:2015 14644-2:2015

Turnkey Cleanroom Construction

Manak is a leader in cleanroom design and construction. We offer design and construction of cleanrooms for economical, fast, state of the art cleanroom facilities according to ISO 14644-1, EU-GMP and ISPE rules.

Our Design-Build Advantages

- Faster Delivery – Collaborative project management means work is completed faster with fewer problems.
- Cost Savings – An integrated team is geared toward efficiency and innovation.
- Better Quality – Design-Builders meet performance needs, not minimum design requirements, often developing innovations to deliver a better project than initially imagined.
- Singular Responsibility – One entity is held accountable for cost, schedule and performance.
- Decreased Administrative Burden – Owners can focus on the project rather than managing multiple contracts.

MANAK Cleanroon Technology

Cleanroom Design Capabilities

Clean Room Construction can modify, refurbish or extend existing cleanroom and containment facilities to meet your changing requirements or to conform to new regulations and standards.

We'll even upgrade facilities that were designed or built by other companies.

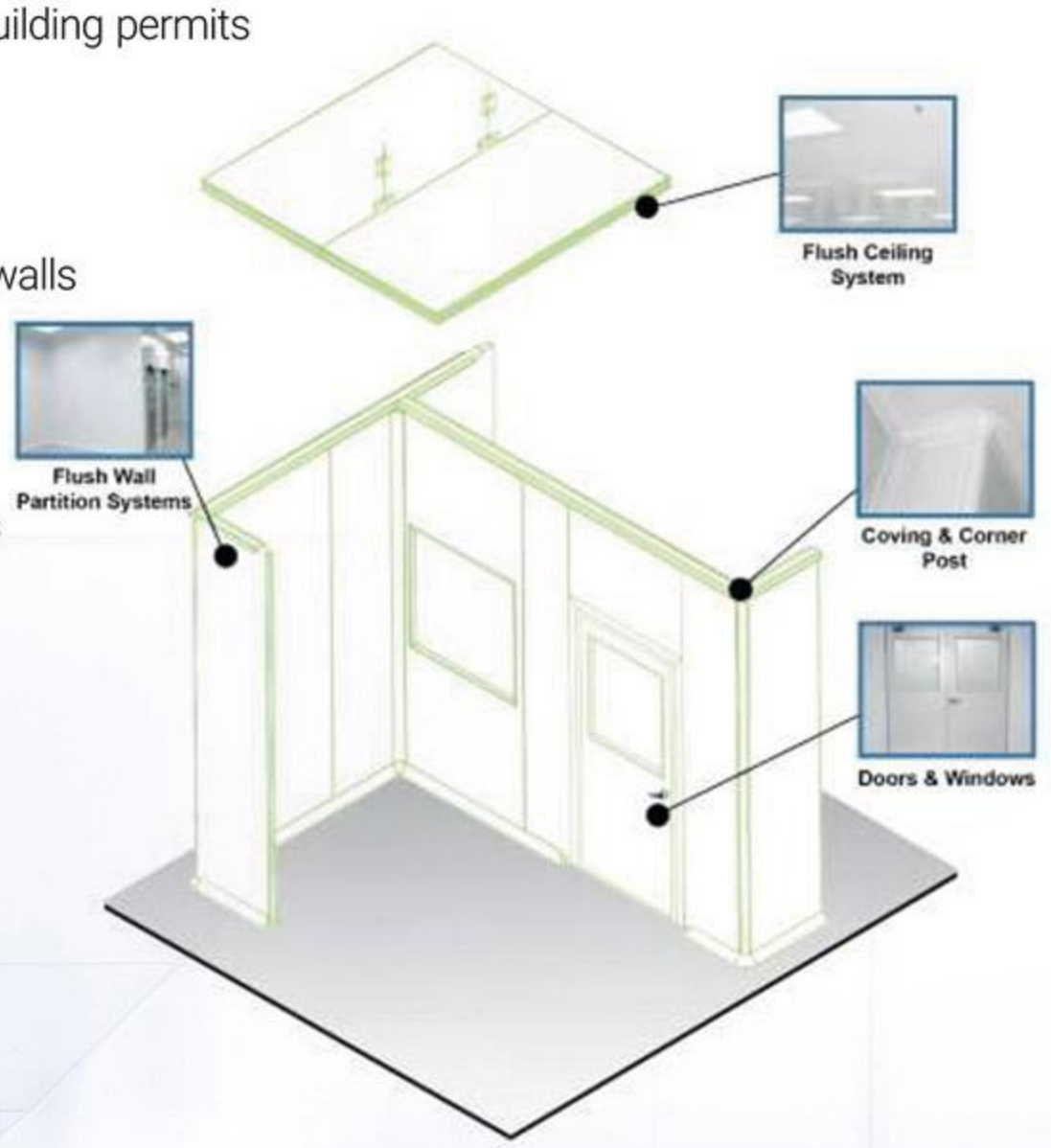
As well as our full turnkey design and build services, we also specialise in the design and installation of flexible modular partitioning systems to meet a growing demand for cleanroom envelope products and services.

Our capabilities include:

- Electrical, and mechanical drawings for building permits
- Cleanroom walls and plenum
- Cleanroom ceiling and lighting
- Cleanroom flooring
- Cleanroom HEPA filtration and return air walls
- Cleanroom HVAC
- Equipment Placement
- Cleanroom certification
- Cleanroom pass Pass-Through, interlocks

Custom Design Based On:

- GMP requirements
- Product flows
- Personnel flows
- Cleaning protocols



Clean Utility

Manak provides detailed design, installation, commissioning and validation services for the following clean utilities' systems.

- PW storage & distribution;
- WFI storage & distribution;
- Pure steam distribution;
- Clean compressed air;
- Clean nitrogen distribution;
- Piping system for other clean media.

Manak team has rich experience in detailed design, installation, commissioning and validation of different processing systems with different utilities and piping.

- Injectable products
- Oral solid dosage (OSD)
- Eye and nasal drops
- Semi solid products
- Oral solution and suspension
- Raw material and API products

Cleanroom Qualification & Validation

We offer a full range of ISO and EU GMP Cleanroom Testing & Validation Services

MANAK are specialists in the testing and reporting of cleanrooms to the ISO 14644 series of classification. The report you will receive following your test meets the requirements of ISO 14644 and if requested EU GMP ensuring client facilities are audit ready and compliant with the requirements of regulatory bodies.

Cleanroom testing and verification requirements

Cleanroom Qualification is the overall process of assessing the level of compliance of a cleanroom or piece of clean air equipment with its intended use. To meet the requirements for BS EN ISO 14644 Parts 1, 2, 3, 4 and 7 a cleanroom must be tested for:

- **Airflow measurement – Volume and velocity.**
- **Airborne particle count.**
- **HEPA filter integrity test**

EU GMP cleanroom testing

- Installed filter leakage and integrity testing.
- Air pressure difference measurement.
- Airflow direction and visualization.
- Microbial airborne and surface contamination.
- Temperature measurement.
- Relative humidity measurement.
- Recovery testing.
- Containment leak test

Clean Room Door & Window

- Clean Room Door
- Emergency Exit Door
- Aluminum Profile Cleanroom Door
- Sliding Door

Door Features

cGMP design

Flush design doors

Custom dimensions

Airtight seal

Automatic bottom drop seal

Both side flush glass

Heavy duty hinges & other accessories

Pharmaceutical Clean Room Door

Pharmaceutical clean room doors combine superior speed, uncompromising quality, dependable reliability and unbeatable value. Designed from the ground up to provide fast opening and closing times for exceptional traffic flow, increased safety and reduced energy costs. Cleanroom Door is manufactured from galvanized steel/stainless steel sheets with lock formed edges.

Emergency Exit Door

The Emergency Exit Panels are specially designed to be used in laboratories with critical environments, GMP and biological safety BSL 3 or higher, being suitable to withstand the differential pressures that characterize these types of facilities.

Sliding Door

These sliding doors for clean rooms are a solution for areas where space is limited. An automatic system allows the opening and closing of the door, which does not have guides on the floor, facilitating the movement of people and cars and avoiding the accumulation of dirt.

Paneling & Walkable Ceiling

The unique design of the ceiling allows the additional incorporating flush light fittings, air-conditioning filters, grills, diffusers and other ceiling mounted equipment, all fitted within accurately CNC punched apertures. Its unique design enables the structure to stand free of any support (box within a box) from the existing building/ structure.

MANAK
Cleanroon Technology

Paneling and ceiling system with silicone sealing.

The walkable panel ceiling system offers a high degree of airtightness against over-pressure and negative pressure through the use of up support profile. An economical system for clean rooms with GMP requirements that meets the highest demands on quality and modularity.

- GMP-compliant
- high grade of air tightness with silicone sealing
- two separate sealing levels
- suitable profiles

Our covings are used to create fully flushed corner transitions and seamless wall-to-ceiling and wall-to-floor connections. PVC & aluminum covings are designed & developed in compliance with the industry standards. Covings are manufactured using quality food grade materials.

Covings can be provided with the following options:

- Aluminum Coving (Powder Coated)
- Aluminum Coving (Anodized)
- PVC Coving

GMP
Training & Consulting

GMP and Regulatory Compliance
Manak Pharmed Co.'s experts can work to evaluate pharmaceutical, biotechnology, or medical device organization to determine if the systems are sufficient to meet GMP (good manufacturing practice) rules and current regulatory standards. We provide comprehensive consulting services to guarantee compliance with PIC/S cGMP and quality system requirement.

GMP Audits
Manak Pharmed Co. provides expert auditors to assess the degree of GMP compliance of its pharmaceutical plants. The audit will identify weak points with respect to the standard and, if necessary, an action plan service is offered with comprehensive advice for the implementation of the necessary actions. Manak Pharmed Consulting will travel to your facility, complete your internal audit, write up with non-conformance findings, and follow-up on the findings to help you meet internal audit requirements and pass your upcoming audit.

GLP (Good Laboratory Practice)
Our GLP team has the experience and capability to conduct audits of all types including: facilities; process data; study specific data and reports against GLP requirements. We audit central laboratories and bio-analytical laboratories for routine and specialized analysis against both GLP and GCP regulations

Risk Analysis
Quality Risk Management (QRM) is a systematic process of risk assessment, control, communication and review to ensure the final quality of pharmaceutical products. Pharmaceutical Quality System, it is necessary to implement risk management in different areas of the Pharmaceutical Industry. Manak Pharmed Co. prepare and improve processes and procedures to avoid all risks, complying with current GMP rules and regulations.

Contamination & Cross Contamination
Contamination is defined as the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into raw material, intermediate, or API during production, sampling, packaging or repackaging, storage or transport. Cross-contamination in pharmaceutical manufacturing occurs when substances or microorganisms are unintentionally transferred between products or processes, compromising product integrity and patient safety.

GMP Training
We provide wide variety of GXP training courses including GMP, GLP, GSP, GDP to pharmaceutical and other industries which can cover GMP Compliance. We have extensive experience providing training to all levels of an organization, from operations personnel to leadership teams to.

GSP & GDP
Good storage practice (GSP) and good distribution practice (GDP) deals with the guidelines for the proper storage and distribution of medicinal products respectively. Manak Pharmed's Experts with many years of experience in pharmaceutical and relevant industries can help you to design and construct different type of warehouses e.g. finished product, raw material, packaging, recall, return, reject and other relevant warehouses based on current rules and standards.

13-14
MANAK
Cleanroon Technology

Manak's
Service at a Glance

EPC (Engineering, Procurement, and Construction)

A turnkey solutions provided for the design, construction, and installation of cleanroom facilities.

- Feasibility Studies
- Conceptual & Detail Design
- GMP Training & Service
- Project Execution
- Feasibility Studies
- Validation & Commissioning

Cleanroom Equipment

- Static / Ventilated / Dynamic Pass boxes
- Horizontal / Vertical / Reverse/ LaminarFlow
- Air Shower

Wall, Ceiling & Floor Systems

Cleanroom in GI / PPGI / HPL / GRP / SS construction with integrated light fixtures & HEPA Boxes

Biosafety cabinets / Stability Chambers

- Microbiological safety cabinets of Classes I, II & III
- Walk-in Stability Chambers

HVAC + AHU's / Filter Fan Modules

HVAC System upto ISO Class 5 with Low-Side, High-Side & Validation

Isolators/ RABS

- Sterility Testing Isolators
- Powder Containment Solutions
- Aseptic / Sterile Isolators

Qualification & Validation

Qualification and Validation Compliance as per USFDA, EU-GMP, WHO, MHRA guidelines and GAMP 5 Compliance

Utilities & Fire-Fighting

- Purified, WFI, Ultra pure Water systems
- Compressed air system
- Steam Generations & Distribution
- Fire Hydrant & Sprinkler System

Integrated Building Management Systems

- BMS with open architecture and Lonworks / Bacnet compatible DDCs
- Pharma Suite ; 21 CFR Part 11 compliant validation software

MANAK

Cleanroom Technology

Manak Pharmed is a Leading Company in clean room design and Construction in GMP related industries.
Manak Pharmed efforts in the field of design, engineering, implementation and validation of clean rooms for pharmaceutical, hospitals, cosmetics and food industries.

Unit 4, No. 1, Arya Bldg., West Sarv, Sa'adat Abad Ave., Tehran, Iran
+98 (21) 26299641
+98 922 8469434
info@manakpharmed.com
www.manakpharmed.com

SCAN TO KEEP IN TOUCH