Our services for legally compliant clean rooms

Clean room measurements with calibrated measuring equipment on the basis of the VDI 2083 and EN ISO 14644 standards:

- Creating a measurement plan
- Determining the measurement points in accordance with EN ISO 14644
- Measurement of the incoming air volume and calculation of the number of airchanges per hour
- Measurement of all climatic parameters such as temperature and relative humidity
- Carrying out filter integrity and leak tests
- Measurement of the concentration of airborne particles and determination of the clean room class
- Measurement of the differential pressures with adjoining rooms or with the atmosphere
- Determining the recovery times - recovery test
- Taking microbiological samples to determine the total amount of CFUs, using an impression tray or sterile pads with dry surfaces and using an air sampler when sampling the air
- Evaluating the samples in a microbiological laboratory to determine the number and type of bacteria, moulds and yeasts
- Overall examination results in a final report, including recommendations
- GMP conforming documentation

We are always there when you need us!

We would be delighted to provide you with more detailed information concerning legal requirements and our range of services. Get in contact with us now and set up a free consultation appointment. **Tel. +49 (0)8031 – 80 78 78 0, info@mmi-gmp.de or on www.mmi-gmp.de**

MMI and partners offer a complete range of services for both small-scale and large-scale projects:

- GMP consultancy
- Hygienic design consultancy
- Operation analyses
- Process re-engineering
- Planning the capacity of your facility
- Layout designing rebuilding, extension or new construction
  Feasibility studies; preliminary, basic and detail designs
- Designing of all technology / clean utilities
  Ventilation, pure water, sterile water, sterile steam, compressed air, electricity, vacuum, etc.
- Procurement management
- Project and construction management
- Clean room designing in accordance with GMP and FDA directives
- Laboratory planning
- Designin cytostatic drug laboratories
- Logistics designing
  Material flow systems, warehousing systems, order-picking systems
- Qualification of your facilities
  DQ, IQ, OQ, PQ; carrying out risk analyses, Creating URS and specifications
- Creating URSs, specifications and SOPs
- Validation of your processes and cleaning measures
- Hygiene inspections in accordance with the German VDI 6022 standard
- Clean room measurement in accordance with VDI 2083 and EN ISO 14644 standards
- Occupational safety consultation

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CLEAN ROOM MEASUREMENT

in accordance with VDI 2083 and ISO EN 14644 standards

Clean Room Measurement – legally compliant and value for money

Clean rooms in the **pharmaceutical industry, for medical devices, in biotechnology, microelectronics or pharmacies** are subject to stringent legal requirements. Regional supervisory authorities are responsible for monitoring.
As an enterprise, you must be able to prove that the **permitted limits** corresponding to your clean room class are not exceeded. Temperature, relative humidity, differential pressure, number of air changes and, in particular, airborne particle concentration and limits for microbial contaminations are all factors which are measured.

Clean room measuring requires a high level of experience and special equipment.

Avoid problems with auditors or with customers!

Authorities and your customers **require regular, legally compliant proof** in the form of **clean room measurements!**

If you, as an enterprise with authorisation to manufacture, do not adhere to the legal requirements detailed in the EU-GMP directive, then you run the risk of severe sanctions from the supervisory authorities. Your authorisation to manufacture can even be withdrawn.

There is a danger that you do not pass supplier audits - you risk to lose customers!

The correct application of standards creates legal security on favourable terms.

Maximum permitted airborne particle concentration in clean rooms

ISO 16466-1 classification	Maximum permitted number of particles per m³ air equal to or grater then the tabulated size - according to EN ISO 14644-1						Maximum permitted number of p air equal to or grater then the t according to EU-GMP-Guid		
							at rest		in
	≥ 0,1 µm	≥ 0,2 µm	≥ 0,3 µm	≥ 0,5 µm	≥ 1,0 µm	≥ 5,0 µm	≥ 0,5 µm	≥ 5,0 µm	≥ 0,5
ISO 1	10	2		4					
ISO 2	100	24	10	35	8				
ISO 3	1.000	237	102	352	83		3.520	20	
ISO 4	10.000	2.370	1.020	3.520	832	29	3.520	29	35
ISO 5	100.000	23.700	10.200	35.200	8.320	293	352.000	2.900	3.5
ISO 6	1.000.000	237.000	102.000	352.000	83.200	2.930	3.520.000	29.000	n
ISO 7				3.520.000	832.000	29.300			
ISO 8				35.200.000	8.320.000	293.000			
ISO 9									

applicable grades for readings and evaluations in the pharmaceutical industry

Sample volume according to ISO 14644-1:

V [l]= 20.000 / C, C stands for max. particle concentration in the bigge
1 m³ for grade A; for grades B, C und D min. = 28,3 l per minute
sicle readings at each reading point

Clean room measurements require professionalism and competency

We have been supporting clean room projects all over the world since 1993. We are a reliable partner in consultation, designing and support concerning clean rooms. Our customers value our **comprehensive expertise**. We possess all the required qualifications and measuring equipment and we have years of experience.
We will gladly prepare a **tailor-made offer** for your individual requirements.

We provide support and consultation with critical measurement results and, together with you, develop appropriate solutions.