



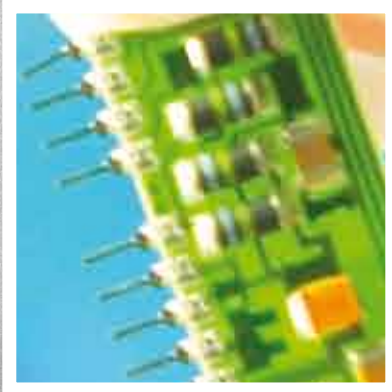
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Succeed with Quality

Cleanrooms acc. to ISO 14644

Cleanrooms and associate controlled environments

High requirements and increasing significance



Motivation and benefits

Cleanrooms are areas where particular attention is paid to the concentration of impurities due to particles and microbial impurities. They are designed as to minimize the development, accumulation and sedimentation of particles disturbing or damaging during the manufacturing process. A cleanroom facility includes all the relevant buildings, air conditioning systems, connections and operating media. Classification of the cleanrooms will be done depending on the sector acc. to ISO 14644, the requirements placed by GMP/FDA or the standards acc. to VDI 2083 and should be done at semi-annual or annual intervals depending on the cleanroom class.

Productions or quality relevant activities and manufacturing processes are steadily expanding from the key areas of cleanroom technology, e.g. microelectronics, aerospace industry as well as pharmaceutical production and healthcare systems, to food industry, precise mechanics, optics, laser technology and PCB (Printed Circuit Board) technology.

The qualification of cleanrooms and clean areas requires a high degree of know-how and use of suitable and adequately calibrated measuring and test equipment. Their execution must conform to the applicable standards and regulations. On the one hand, this is to make it possible to reproducibly identify cleanroom quality. On the other hand, it also is to help to pass on this standard to public authorities and customers.

A cleanroom audit

- represents independent review of the normatively specified procedure for classifying a cleanroom
- is conducted by trained and experienced auditors of Quality Austria
- is documented by means a Certificate valid on an international scale

Objectives

- quality assurance in the cleanroom, which ranges from planning via installation and operation to performance
- independent demonstration of quality/the level of production environments
- minimizing customer audits
- benchmark comparabilities in the production process
- marketing effect, e.g. our production is done in certified cleanrooms of Class

Target group

Organizations active in the following fields:

- nano-tech and precision mechanics
- aerospace industry
- microelectronics, electrical engineering, surface treatment
- medical technology, hospitals
- genetic technology and bio-technology, pharmaceutical industry
- laser technology, glass fibre technology and PCB technology (PCB – Printed Circuit Boards)
- food sector
- laboratories

Identification and labelling

Identification and labelling of the particle purity in a cleanroom will be done according to the criteria of ISO 14644 and must include the following items.



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- Classification Number, e.g. ISO Class 7
- the operating state to which the classification applies
- the considered particle size, e.g. 0.5µm or 5µm

Basic requirements

The basic requirement is compliance with specified contamination classes. A distinction is made between nine ISO Classes.

Critical parameters

Critical parameters of cleanrooms are:

- air cleanliness, air exchange rate, air volumes
- choice of the adequate cleanroom class
- clothing in cleanrooms
- choice of suitable operating materials
- air filters, filter classes, mode of action of filters
- planning of sluices and access areas

Training

In order to provide you and your production team with the required know-how relating to functional modes, quality relevant processes, impurities due to particles, cleanroom clothing and the behaviour in the cleanroom and to familiarize you and your production team with the technical requirements and processes of cleanroom technology, Quality Austria offers a comprehensive training program relating to cleanrooms. On the one hand, seminars that are attended by many participants give you the chance to be trained in the latest findings and developments. On the other hand, they enable you to discuss and exchange your own experience with our experienced technical trainers as well as with other persons participating in the seminars.

Other relevant standards

ISO 9001, HACCP, ISO 14698, GMP, VDI 2083

Quality Austria introduces itself

Quality Austria Training, Certification and Evaluation Ltd. is your competence partner for integrated management systems in the fields of quality, environment and safety and industry standards as well as business quality. The services provided by Quality Austria range from trainings in the field of international management trends and techniques via certification of management systems according to international standards and regulations and national guidelines and directives and assessments acc. to the EFQM Excellence Model to awarding the Austria Quality Seal. The Austrian Quality Award will be presented to Austrian organizations in co-operation with the Federal Ministry for Economic Affairs, Family and Youth. Quality Austria Ltd. is accredited by the Federal Ministry for Economic Affairs,

Family and Youth and has numerous international registrations and accreditations.

Having more than 550 auditors, trainers, assessors and technical experts, Quality Austria secures successful implementation of standards and regulations within the organizations and provides sector and product specific know-how with a very high focus on practical work. Based on the competence network in the field of comprehensive sector specific, technical and methodological knowledge as well as comprehensive experience, trends will be influenced while innovations will be interpreted and tomorrow's requirements will be co-designed actively and consistently in corresponding bodies even on an international scale.

The close connection of Quality Austria as a national representative with the international partner organizations IQNet, EOQ and EFQM as well as co-operation of Quality Austria with IPC, VDA-QMC and IATF enable global know-how to be imparted and turn the organization into a competent partner. Quality Austria co-operates with about 100 member organizations world-wide. More than 12,000 organizations in little less than 50 countries already profit from this. Quality Austria is a stable factor when it comes to creating valuable synergies at the economic site of Austria.

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