

# ISO 14644

## Cleanrooms and associate controlled environments



### 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 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 EN ISO 14644, the requirements placed by GMP/FDA or the standards acc. to VDI 2083 and should be done at annual intervals.

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, 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 and
- is documented by means a certificate valid on an international scale.

### OBJECTIVES

- quality assurance in the cleanroom including planning, installation, operation qualification and performance qualification
- independent verification of quality / the level of production environments
- minimizing customer audits
- benchmark comparabilities in the production process

- increase of the reputation among stakeholders, e.g. our production is done in certified cleanrooms of Class 5 (acc. to EN ISO 14644/1)

### TARGET GROUP

Organizations active in the following fields:

- nano-technology 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





## LABELING

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:

- 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

There is a normative difference between cleanroom classes 1 (highest purity level) to classes 9. The basic requirement is to ensure and document the permanent conformity to the selected cleanroom class.

### 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

## OTHER RELEVANT STANDARDS

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

## QUALITY AUSTRIA – WHO WE ARE

Quality Austria Holding GmbH, together with its operational subsidiaries Quality Austria Academy GmbH and Quality Austria Certification GmbH, is Austria's leading authority for training and continuing education as well as for certifications of individuals, systems, and products, inspections and validations, assessments, and the Austria Quality Seal. This is based on globally recognized accreditations and international approvals.

Since 1996, the company, in cooperation with the Federal Ministry of Labor and Economy (BMAW), has also awarded the State Prize for Corporate Quality. As the national market leader for the Integrated Management System aimed at ensuring and improving corporate quality, Quality Austria is a driving force for Austria as a business location and stands for „Success with Quality.“

Quality Austria collaborates globally with around 1,000 network partners and more than 20 organizations and is actively involved in standardization committees as well as international networks such as EOQ and IQNET. Since its founding in 2004, Quality Austria has conducted over 185,000 audits, assessments, and inspections, and more than 100,000 individuals have attended the courses and in-house trainings offered by the internationally operating company



**Thomas Waldner**  
Business Development  
Integrated Management System  
thomas.waldner@qualityaustria.com

