qualityaustria
Succeed with Quality

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

We are the leading Austrian contact for the Integrated Management System, based on quality, environmental and OH&S (occupational health and safety) management, and the topic of business excellence. Our main focuses are system and product certification, training and personal certification. We are accredited by the Federal Ministry for Digital and Economic Affairs (BMDW) for system, product as well as personal certification and have many international registrations and accreditations. Furthermore, we present the Austrian Excellence Award together with the BMDW and award the Austria Quality Seal.

Additionally, we organize several forums and conferences and have issued numerous publications. We participate actively in standardization bodies and international networks such as EOQ, IQNet and EFQM. We cooperate with some 50 partner and member organizations worldwide and thus ensure the facilitation of global know-how.

Having more than 1.000 auditors, trainers, assessors and technical experts all over the world, we ensure the successful implementation of standards and regulations within the organizations and provide sector and product specific knowledge with a very high focus on practical relevance. More than 10.000 customers in approx. 30 countries and over 6.000 annual participants in our trainings benefit from the long-standing expertise of our organization. We adapt our offer according to our clients' needs and support them in achieving their long-term goals!

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Doc. No.: RE 24_00_03_e, Edition: March 2020