›Clean‹ Explosion protection

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Figure 1: Tip of the reactor in the upper floor

Cleanroom technology can be found everywhere in industry. Very stringent requirements are placed on technology and air purity in production, processing and assembly of electronic equipment, precision mechanics and optics or in the pharmaceutical sector, biotechnology and foodstuff production. Quality of the products and frequently also health of staff can be guaranteed reliably only by compliance with defined degrees of air purity in the workplace.

Frequently, flammable and combustible substances in the form of fluids or dusts are also used in these processes. Of course, in an undisturbed state, these substances are in closed apparatus but they may be released in the event of malfunctions or when cleaning with flammable liquids. Consequently, the requirements of explosion protection must also be met in cleanrooms. The article below illustrates how this is done.

Overview of cleanroom technology

In general terms, cleanroom technology has the task of protecting certain work areas from undesired external influences. The external influences occur in the form of contamination that may be either gaseous or solid, or may comprise liquid particles of various sizes.

The harmful effect of these particles may impact in different ways:

- Increasing miniaturisation, characteristic most clearly in microelectronics and microengineering, means that even minute quantities of tiny process contaminants may lead to sustained impairment of product quality. This fact becomes clear if we consider the structure sizes typical today in microelectronics, specifically the submicrometre range, and if we compare these sizes with the average size of a grain of house dust, which is a few orders of magnitude larger.
- Production of many pharmaceutical products requires a very aseptic environment. Germs, dust and microorganisms in particular have a negative impact on quality of the preparations and may, under certain circumstances, also lead to side-effects detrimental to health.
- Many of the active ingredients used in the pharmaceutical sector are highly active and toxic. Even contact with minute quantities of these substances may seriously damage the health and safety of those employed in production.

Consequently, and generally speaking, cleanroom technology involves protection of products, equipment and production processes against contamination-related damage or performance slumps while at the same time it involves protection of the individuals working in production processes against process risks harmful to health. This is done by providing working environments with a precisely specified air purity in relation to airborne particulate process contaminants.

Planning and construction of cleanrooms require close cooperation between the subsequent user and the company constructing the system so as to comply with the set air purity requirements at a feasible expense. The solution implemented must be adapted optimally to the relevant application. Important input parameters are various process requirements such as the number of persons working simultaneously, the need for protective equipment, heat development, the substances to be used, the required purity expressed in purity classes, the installation density, and the building structure. Frequently, many public-authority regulations also need to be met.

The close connection between design of the cleanroom and the relevant application may be one reason why the many international and national standards and guidelines on the topic of cleanroom technology were very disparate and fragmentary for a long time. It is only in the last few years that there has been a perceptible development allowing manufacturers of cleanroom equipment to supply standardised products for various applications (see reperated text).

It must be guaranteed that all critical cleanroom parameters, i.e. temperature, relative humidity, differential pressure and particle count, are recorded and documented in ongoing fashion in order to be able to ensure safe and reliable batch production in subsequent operation.

Owing to the increasingly stringent requirements applicable to ambient conditions when manufacturing and filling sales containers with medicines imposed by international and national authorities such as the WHO, the EU and the US Food and Drug Administration (FDA), continual monitoring of the ambient conditions and absolutely complete documentation of the data recorded during the process have become far more important.

The oldest and internationally most heeded Standard on cleanroom technology is US Federal Standard 209 that includes a classification of air purity classes. Another classification of cleanrooms can be found in ISO 14644-1.

There are other guidelines and directives on design of the cleanrooms and monitoring of the cleanroom conditions, specifically for the pharmaceutical sector. One of these, by way of example, is the 21 CFR 11 Rule of the American Food and Drug Administration in relation to process tracking and process documentation, the cGMP Directive of the European Community that defines targets for Good Manufacturing Practice (GMP).

In Germany, VDI Recommendation 2083, Sheet 8 ›Reinraumtauglichkeit von Betriebsmitteln‹ (Cleanroom Capability of Apparatus) describes the requirements of this specific application. The Guideline that was published in July 2002 distinguishes between the requirements in respect of cleanroom compatibility and compatibility of the required cleanliness. The term cleanroom compatibility covers the properties of an apparatus that in itself acts as the source of impurities. Compatibility with cleanliness requirements describes properties such as cleanability and mechanical resistance of the technical surfaces, characteristic electrostatic parameters, and biocompatibility of the materials used.

Explosion protection in cleanrooms

The substances and active ingredients used in cleanrooms are very frequently inflammable or combustible, both in dust form and in liquid form, and may consequently, form a hazardous, explosive atmosphere together with atmospheric oxygen. Admittedly, most processes occur in closed apparatus owing to the special requirements applicable to ambient conditions, but there may also be ➔

Figure 2: Operator Station on reactor

process steps in which small quantities of substances are handled outside of enclosed containers, for example when filling containers with substances in dust or liquid form. In addition, it is also necessary to allow for various installation statuses in which no cleanroom conditions are maintained, but in which there may be a risk of explosion when determining the explosion risk. Such installation statuses are, for example, trial runs, start-up, and both test and maintenance procedures.

Cleaning processes represent a special aspect. Frequently, solvents need to be used for thorough cleaning of the rooms and apparatus. Even if no inflammable substances are used in the process, this necessarily leads to classification as a hazardous area.

The classification of hazardous cleanrooms itself is based on the nature of the inflammable and combustible substances used and the frequency of occurrence of an explosive atmosphere.

Example of a cleanroom installation with hazardous areas

Below, we will explain the explosion protection measures in cleanrooms on the basis of a recently commissioned installation of a large pharmaceutical product manufacturer.

The stringent purity requirements relate to the process on the one hand and relate to the fact that certain highly reactive substances are present on the other hand.

The installation was planned over a period of three years and constructed over several stages in an existing building. The required explosion protection measures must be taken since flammable solvents are used for regular cleaning of the rooms.

The topmost level accommodates what is called the reactor chambers (Figures 1 and 2). The term is a little misleading because the large reactors are installed vertically over several levels within the building, and these chambers cover only the tip of the reactor. Owing to the fact that the processes are largely closed processes, there are no special requirements in respect to the maximum permitted particle concentration in the chambers, but there are special requirements for cleanability of the room and equipment.

It must be possible to thoroughly and easily remove contamination in order to protect personnel.

The installation's automation system is based on internetworked Remote-PCs that are not linked to a higher-level process control system and a Fieldbus System (Profibus PA), suitable for Zone 1, which networks the sensors and actuators that are able to communicate. The processes in the relevant room are controlled directly via the Remote-PCs. Remote control from one room to another is not possible and only safety-critical commands can be transferred to another PC.

The mixing room (Figure 3) is located one level lower. This is where the substances undergo a process referred to as ›predetailing‹, i.e. pasty substances are produced by mixing various starting substances using solvent.

Since this largely involves exposed handling of the starting substances, more stringent requirements are made of the process purity, and a maximum impurity of 100,000 particles per cubic foot may not exceed.

All walls are made of stainless steel and are designed to prevent the formation of dust deposits and to allow easy cleaning. The floor was sanded and painted several times. Stainless steel built-in

Figure 3: Mixing room

Figure 4: Access lock with explosion protected stainless steel build-in ceiling light fitting

ceiling light fittings of equipment category 2 are used for lighting. The special working requirements demand high illumination in this area. For reasons relating to personnel safety, personnel may only enter both the mixing room and the reactor chamber when wearing an artificially protective suit and through a personnel lock (Figure 4). The above-mentioned built-in ceiling light fittings are also used here.

Attention is paid to strict separation of personnel traffic from material transport throughout the entire installation. This is why there are separate locks for the material as well as for the personnel locks.

The ground floor houses the lower section of the reactor. This is where the reaction products are removed and further-processed with centrifuges and various driers (Figures 5 and 6).

The basement level houses various tanks, some of them serving to collect the effluent and some of them performing a safety function (Figure 7).

The entire reactor fluid is collected in a tank in the event of an emergency shutdown of the installation. No special purity requirements apply to this area, however, explosion protected apparatus, such as linear fluorescent luminaires (Zone 2) as well as both safety switches and operator terminals (Zone 1), are installed owing to the possibility of explosive atmospheres being released.

Figure 5: Discharge point on the centrifuge with explosion protected control board

Figure 6: Explosion protected control device for controlling the product release

Figure 7: Effluent collecting depot with explosion protected operator display

Summary

Two typical niche industries whose importance arises from the special aspects of certain industrial processes are cleanroom technology and explosion protection.

While cleanroom technology covers protecting both products and personnel, the task of explosion protection is to protect persons and installations against the hazardous effects of uncontrolled process reactions.

The technical and organisational requirements applicable to cleanroom technology and explosion protection essentially differ.

Consequently, close cooperation at an early point between planner, installation operator and the manufacturer of the explosion protected equipment is required in order to avoid unnecessarily high expenditure when constructing installations requiring both cleanroom technology and explosion protection.