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A short Introduction to Cleanliness Technology: Meeting the future Challenges

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Abstract

For semiconductor components, the demand to improve performance and velocity as well as energy consumption is met through miniaturization. The continuing trend to miniaturize semiconductor structures can be observed since several decades and requires, among other things, sophisticated cleanliness technology. Cleanliness technology in this context is to be understood as the chain of all activities taken to control and reduce all contamination harmful to the product. Because of the very challenging particulate and outgassing contamination levels, semiconductor industry still claims technological and economic leadership in terms of cleanliness technology. But no longer only semiconductor industry is relying on cleanliness technology as the following case studies graphically demonstrate:

In life science industries, mainly microbiological contamination is controlled to prevent users and patients from severe health issues caused by poor hygiene or cleanliness of the highly effective pharmaceuticals or very innovative medical devices.

Space exploration combines nowadays the challenging cleanliness requirements of semiconductor and pharmaceutical industry to be in compliance with the planetary protection program, the guiding principle to preserve planetary and terrestrial conditions for future generations.

And even automotive industry discovered the benefit of cleanliness technology almost ten years ago: Metallic micro sized particles (>50µm) were identified as critical contamination because they can cause malfunctions in fluidic and electronic vehicle systems such as antiblocking systems.

By having a closer look on these three case studies, the increasing importance and on-going diversification of cleanliness technology can be shown and also the challenging future requirements of cleanliness technology over the next few years can be derived.

Key words: Cleanliness Technology, Cleanroom Technology, Contamination Control, Medical Devices, Pharmaceuticals, Semiconductors, Space Exploration, Flight Hardware, Automotive.

1. Introduction

The knowledge about cleanliness is very old and dates back to ancient times when medicines first recognized the importance of microbiological cleanliness, in this context often called “hygiene”. The first scientific cleanliness technology approaches in modern times were also made by medicines like Semmelweis and Lister. Their proposed disinfection methods established in hospitals and operating rooms reduced the infection and mortality rate of patients dramatically. The acknowledgement of their work in sciences finally resulted in the awareness that there is critical "invisible" contamination and that such contaminants must be controlled. At the very beginning, this principle was mainly applied to protect human health and safety. But soon, starting at the first half of the last century, this knowledge was also transferred to the production of contamination sensitive products, components and systems, e.g. integrated circuits, flat panel displays, hard disk drives, PV modules, pharmaceuticals, medical devices, automotive turbochargers - and so on and so forth. This list of examples could be continued almost ad infinitum and demonstrates the

daily increasing and highly diversified application fields of cleanliness technology. In this understanding, cleanliness technology means the chain of all activities taken to control and reduce contamination harmful to the product as well as human health (Gail et al 2012).

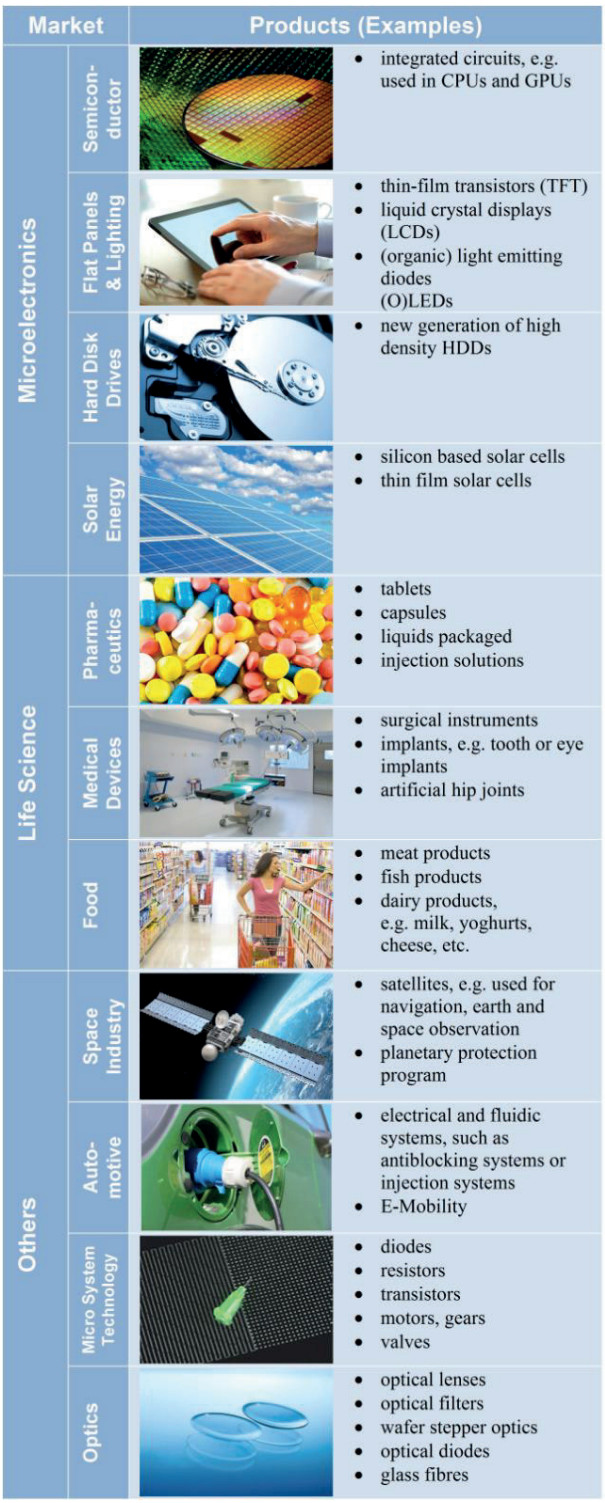

Figure 1. Overview of markets (incl. exemplarily shown products) relying on cleanliness technology. Image Source: Fraunhofer IPA and Shutterstock

Depending on the branch of industry and process concerned, different forms of contamination have a damaging influence on the product. An industrial survey carried out by Fraunhofer IPA in 2003 confirmed that the greatest problem in clean manufacturing continues to be submicrometer-sized particles, followed by molecular contamination (outgassing), electrostatic discharge phenomena (ESD) and microbiological contamination (Gommel 2006).

To reduce the contamination to a non-critical, tolerable level, cleanroom technology as one very powerful instrument of cleanliness technology was developed, mainly to remove biotic and abiotic particles from the production environment by a constant air filtering, air exchange and aircirculation.

Because of the very challenging contamination levels, semiconductor industry still claims technological and economic leadership in terms of classical cleanliness technology. But no longer only semiconductor industry is relying on this technology (Figure 1). The following three case studies out of different industry branches demonstrate the increasing importance, on-going diversification and future challenges of cleanliness technology.

2. Life-Science Applications

2.1 Short Market Analysis

"We are finally entering an exciting time in medicine where we have the technology to custom-tailor treatment and preventive protocols just as we'd custom-tailor a suit or designer gown to one's individual body." (Agus 2011)

This quotation originates from the 2011 published book "The End of Illness" written by David Agus, oncologist and attending doctor of Steve Jobs. It testifies the trend that medicine owes new therapy options mostly life science innovations, e.g. tailored cytostatics, i.e. drugs to inhibit cell division, for highly efficient cancer therapies. In consideration of the approx. 7 million people who died of cancer in 2010 worldwide (Mukherjee 2010), an outlook that gives hope and that justifies also the economic importance of the life science branches. A closer look on medical technology confirms this: In 2005, only this industry branch generated a turnover of approx. 190 billion EUR, mainly spread between the world market leaders U.S.A. (~40%), Japan

(~10%) and Germany (~10%). Also the growth prognosis is very promising: A steady growth of approx. 3-4% p.a. over the next five years is forecasted (Deutsche Bank Research 2008). This is due to the fact that, in conjunction with the demographic change, people in the industrial countries will have an increased life expectancy over the coming decades. Therefore the demand for pharmaceuticals and medical products is expected to rise in order to maintain the quality of life. These developments make the prediction of Gerard Kleisterlee, the former CEO of Royal Philips Electronics, the world's third largest manufacturer of medical devices, comprehensible: *"Medical technology is the growth market of the future"*.

2.2 Specific Contamination Control Aspects

The trend in medical technology is currently towards innovative, long-lasting, high-quality products with the aim of optimising patient benefits and keeping physical and psychological stress as well as costs as low as possible. In view of the extremely high and continually growing demands placed on medical devices, the industry needs a high innovation potential. This is partially reflected by the fact that German medical technology companies achieve over 50% of their turnover with products that are less than two years old (BMBF 2005).

To be competitive in the life science markets, high quality products are required to protect the human health and safety of patients and operating personnel (medicines, nurses, etc.). Because very often the products are in direct contact with human tissue, the infection risks caused by microorganisms have to be considered carefully (Figure 2).

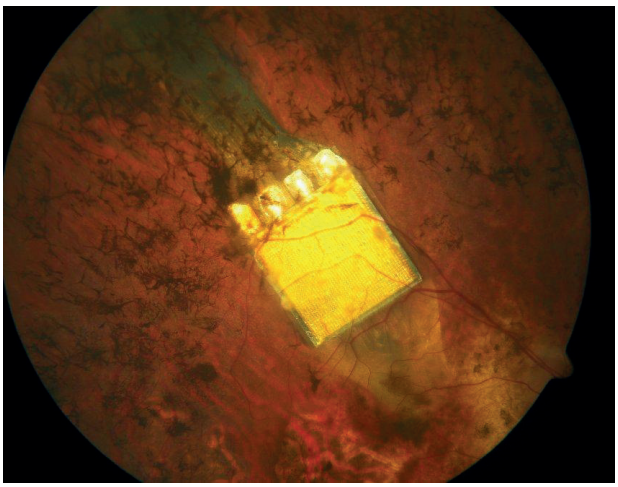

Figure 2. Example of a 3 x 3 mm implanted artificial retina chip implanted in a human eye. Source: Retina Implant AG, Tübingen.

Therefore, also the cleanliness of medical devices, like medical machines, reusable surgical instruments, implants and artificial hip joints, moves more and more into the public focus.

The following facts and figures also make the hygiene and cleanliness issues of medical devices very clear:

- Increasing number of nosocomial infections in hospitals: only in Germany approx. 500,000 infections per year, 10,000 of them (equates to 2%) lethal (BMG 2011).
- Recall campaigns initiated by the FDA: 243 recalls in the years 2001 to 2011, 64 of them (equates to 26%) because of cleanliness issues, upward trend in the last years (FDA 2012).

Although the knowledge that cleanliness is important for medical devices is available since many decades and written down in numerous national and international guidelines (e.g. the European Union legal framework for medical devices consists of the three directives 90/385/EEC, 93/42/EEC and 98/79/EC and defines basically four risk classes for medical devices, ranging from low risk to high risk), there are still problems caused by poor hygiene or cleanliness. The hygiene and cleanliness of medical devices has meanwhile also an economic dimension: Due to rejection reactions and inflammations, e.g. of implants, post treatment costs arise, in Germany estimated 7 billion EUR per year (Kramme 2007).

However, the cleanliness validation, i.e. the inspection of the cleanliness state of products, instruments or other surfaces in the medical device environment lags behind. Methods for cleaning or sterilization are validated using only qualitative approaches like visual inspection. Quality assurance is often limited to the compliance with standardized processes, not on inline inspections to directly monitor the cleanliness or sterility.

2.3 Suitable Cleanliness Validation

At this point it is worth thinking outside the box. In particular, new measuring techniques provide new approaches for conducting quantitatively cleanliness validations of the most critical contaminants, i.e.

- particles (abiotic and biotic) and
- thin-film contamination (e.g. organics like lubricants from process tools, finger prints, etc.)

even on complex shaped products (direct or indirect, Figure 3).

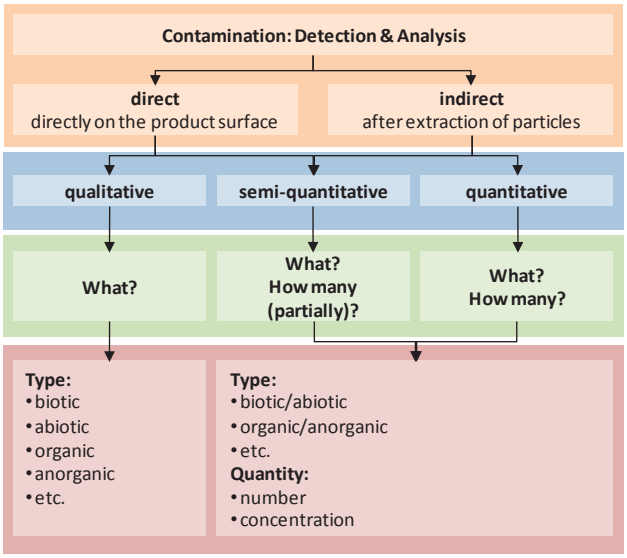

Figure 3. Approaches to detect contamination on surfaces for the quantitative validation of the cleanliness state.

3. Space Flight

3.1 Short Market Analysis

At first glance, space industry seems to be a niche. But at second glance, the global space revenue from government and private activities reached in 2008 more than 257 billion USD (Space Foundation 2008). But actually, this isn't really surprising if you have a closer look. A lot of technological space flight achievements are unnoticed but an indispensable part of modern life. Navigation systems, telecommunications, as well as weather and climate forecasts are inconceivable without satellites in space. And the numerous interplanetary space missions, for example the exploration of Mars, can influence the quality of life here on earth in many positive, yet unforeseeable ways: generation of new scientific knowledge, exploration of new habitats or exploitation of natural resources are only a few facets of such visions.

3.2 Specific Contamination Control Aspects

"Failure is not an option" is not only a slogan for space flight. To fulfil the very challenging requirements in regard of durability, reliability and performance of satellites and spacecrafts under extremely stressful conditions in space, nothing less than the best available cleanliness technology is good enough to be on the safe side.

In addition to improving performance and reliability, internationally ratified "Planetary Protection" requirements have to be considered, especially for extra-terrestrial space missions, e.g. for the search of life missions. According to this policy, neither may terrestrial life forms, i.e. microorganisms such as bacteria and spores, contaminate outer space, nor may the earth be contaminated by unknown life forms from sample return missions. All this is done to minimize influences on evolution as well as to avoid falsified results and misinterpretations on search for missions. Thus, space flight combines the very challenging contamination control requirements of semiconductor industry (particles, molecular contamination, ESD) and pharmaceutical industry (microbiological contamination).

To guarantee the specified cleanliness levels of the flight hardware, cleaning processes are necessary. This in turn means to choose suitable ultraprecision cleaning technologies as well as suitable concepts to avoid a recontamination of the cleaned flight hardware during the assembly and integration phase. Sophisticated concepts to take this all into consideration are being developed currently.

3.3 Validation of Cleaning Technologies

So far, there is less validated knowledge about the quantitative efficacies of cleaning technologies available. Thus, in the first place, a suitable validation concept of cleaning technologies is required. Main problem of such a concept is to avoid crosscontamination from the environment and the operator. Hence, all validation steps have to be performed in an AMC ("airborne molecular contamination") controlled ISO Class 1 cleanroom according to ISO 14644 by skilled cleanroom operators. The main test principle is to contaminate representative test samples in a defined way and to determine the contamination quantitatively before and after the cleaning process. This can be done using the following measuring and analysing techniques:

- To detect particles on surfaces, scanning electron microscopes (SEM) can be used which can count particles automated on a surface due to the material contrast down to nanometre sizes.
- To detect organic molecular contamination, a gas chromatograph combined with a mass spectrometer (TD-GC/MS) can be used.

All measuring and analysing techniques have to be of course installed in the mentioned controlled clean environment.

CO_2 snow cleaning is a very promising ultraprecision cleaning technology for space

applications because it can remove particulate (biotic and abiotic) and molecular (organic) contamination at the same time very effectively. With the described approach, it could be proven that CO_2 snow cleaning is a suitable ultraprecision cleaning technology for space flight because it fulfils the high requirements of the planetary protection policy (Figure 4). Also other cleaning technologies can be validated with this approach to make the cleaning efficacies of different cleaning technologies comparable for the first time. Of course, such concepts can be also transferred to validate the efficacies of cleaning technologies relevant for other branches like semiconductor, pharmaceutical or medical device industry.

Figure 4. CO_2 snow cleaning as ultraprecission cleaning technology (left) used in the precision cleaning cleanroom at ESTEC (right).

3.4 Clean Assembly Environment

The cleaning procedures for the flight hardware require a clean environment fulfilling the same requirements as described for cleaning technology validation to avoid any critical crosscontamination during the assembly and integration, i.e. an AMC controlled ISO Class 1 cleanroom. All operators have to be specially and regularly trained. And also sophisticated material and personnel flows have to be designed. Such a cleanliness technology was newly installed at the European Space Research and Technology Centre (ESTEC) in Noordwijk, Netherlands. The dissemination of the knowledge about contamination control for space applications is guaranteed by the ESA initiative "European Cooperation for Space Standardization (ECSS)" that makes the knowledge available to public in manifold product quality and management standards.

4. Automotive Industry

4.1 Short Market Analysis

In the year 2011, worldwide almost 60 million automobiles were produced and nearly 1 billion cars and trucks were on the road (OICA 2012). Only these figures show the impact of this industry branch, even if it is known as a very cyclic industry. But automotive industry has also a reputation of being one of the biggest polluter: particulate matter emission and climate change due to CO_2 emission are only two key aspects in this connotation. In consequence, a very high innovation potential of the automotive companies is needed to survive in this internationalized market.

Therefore, to reduce gas consumption in conjunction with CO_2 emission and also to increase safety, new materials (e.g. carbon fibres laminates used for light construction), new techniques (e.g. efficient common rail direct injection engines or electric motors) and sophisticated vehicle systems (e.g. electronic stability programs or antiblocking systems) have to be developed and implemented. To support these developments, many governments have provided research funds. For example the E-Mobility activities of the German government are targeted on the goal of one million electric vehicles on the road until the year 2020 (situation in 2011: approx. 4,500 registered electric vehicles and approx. 50,000 registered hybrid vehicles, Automobil Industrie 2012).

4.2 Specific Contamination Control Aspects

Figure 5. Damaged connection rod (left) and cylinder (right). Failure reason was a continuous gas injection caused by a micrometre sized particle.

During the last ten years, the following quality problems could be observed: residual particulate contamination, mainly metallic particles >50µm, caused various functional impairments, e.g. in many fluid circuits found in automobiles (fuel systems, brake circuits, lubricating and hydraulics systems, cooling and air-conditioning systems, air intakes or exhaust systems and further treatment, etc.) as well as in mechanical and electronic units. Even very small amounts can cause severe problems (Figure 5).

Sources for critical particles are mainly production, handling and assembly processes. But even if you

use sophisticated cleanroom concepts for production and assembly or cleaning steps at critical process points, the risk of particulate contamination can't be completely eliminated. Thus, in any case, all relevant system components are generally cleaned after manufacture and the level of cleanliness needed for them to function must be specified and inspected.

4.3 Cleanliness Inspection (VDA Volume 19)

The VDA 19 (2004) guideline describes the conditions for applying inspection methods for determining the particulate contamination state of components, carried out in the following three steps (all steps have to be performed in a sufficient clean environment):

- extraction of particles (e.g. rinsing)
- filtration
- analysis (e.g. automated particle counting using light microscopes or scanning electron microscopes, if possible with material/element analysis, e.g. energy dispersive X-ray analysis)

The particulate cleanliness state of a component represents a characteristic of functional quality. The quantity of contamination determined on it is dependent upon the inspection method used. Therefore, appropriate inspection specifications are to be agreed upon between the customer and the supplier before commencing the inspection.

4.4 Clean Assembly (VDA Volume 19.2)

The VDA 19.2 guideline is an aid to plan new assembly areas and environments as well as to optimize existing ones in regard of contamination control by the following approaches:

- prevent the generation of critical particulate contamination at sensitive sites,
- remove unavoidable particles,
- protect components and assembled systems against the entry of particles from the surroundings and
- avoid recontamination of initially clean components through transportation, storage, provision.

As not every particle source in a considered environment is automatically critical to the function of a completed product, the guideline also aims to name the relevant sources. This is required in order to take the correct technical and cost-effective measures and to avoid unnecessary costs having no appreciable benefit for the end-product.

5. Conclusions

The semiconductor industry is still the classical and most driving force for further developments in cleanliness technology, especially in cleanroom technology. But the three case studies out of the life science, space flight and automotive industry demonstrated that no longer only this classical semiconductor branch is relying on the use of cleanliness technology: Almost daily new markets are discovering the advantages of a certain cleanliness level on the product quality and reliability. By transferring the already established cleanliness technology to other industry branches, synergy potentials may be used and in consequence, the diversification of cleanliness technology leads to an evolution of already established cleanliness methods and concepts. Thus, cleanliness technology keeps being a fascinating, fast growing market in future.

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