10 ESSENTIAL QUESTIONS ABOUT CLEANROOMS

km
Purely Advanced

10 ESSENTIAL QUESTIONS

ABOUT CLEANROOMS

Purely Advanced

THE RIGHT SOLUTION AGAINST CONTAMINATION

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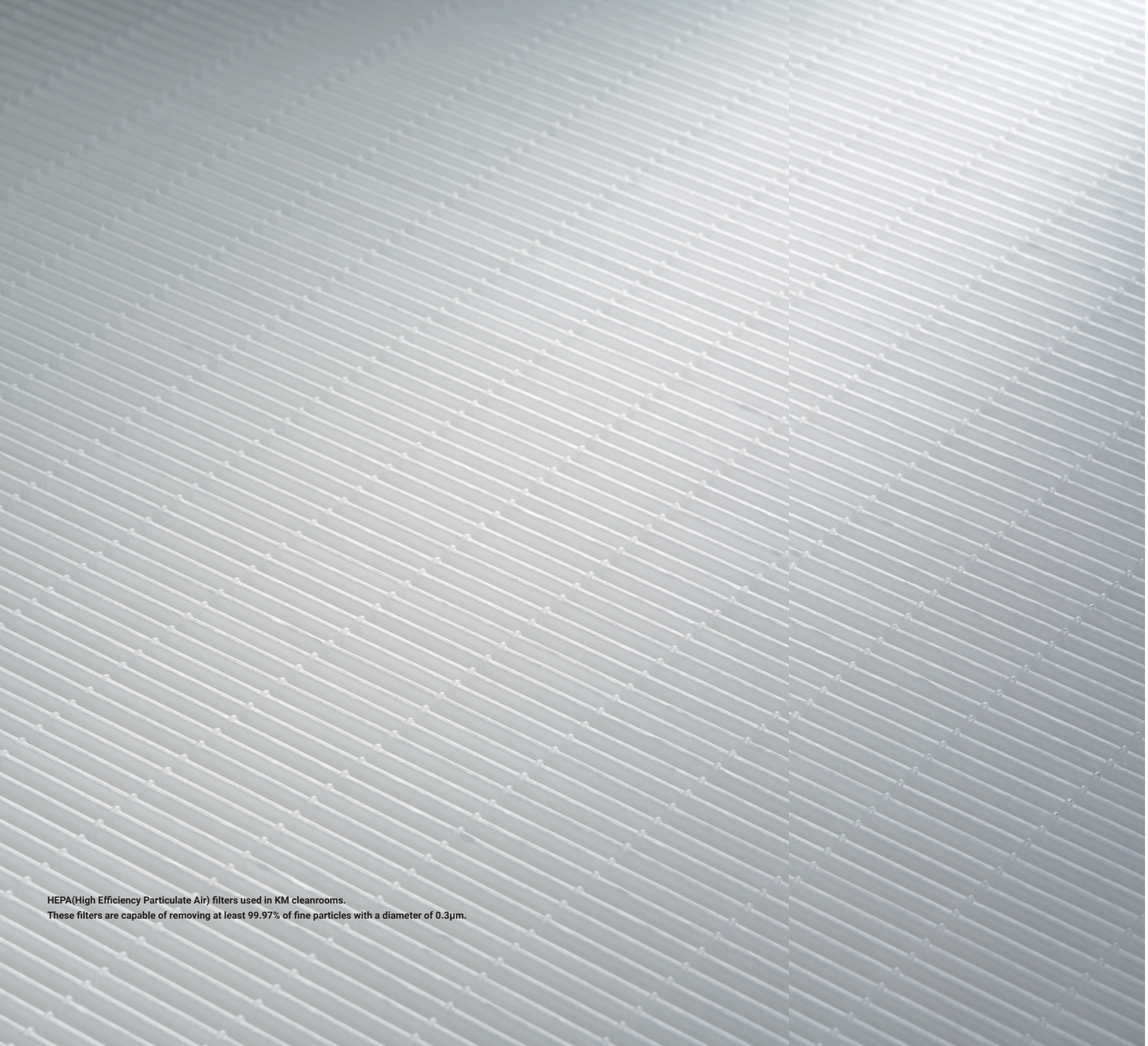
10 ESSENTIAL QUESTIONS ABOUT CLEANROOMS

This book serves as a comprehensive guide to cleanrooms, covering everything from definitions and contamination control methods to operational principles, usage procedures, and overall management. With ten intuitive questions, it provides an accessible foundation in cleanroom knowledge.

Each question is accompanied by follow-up questions that encourage deeper exploration, while the “KM Story” sections offer insight into KM’s unique work approach and philosophy. Readers are free to start anywhere in the book, but beginning with the first question, “What is a cleanroom?” is recommended for a structured understanding, as a solid foundation is essential for a complete grasp of this specialized field.

Since 1989, KM has been dedicated to producing high-quality cleanroom products, building unique technical standards through relentless research and development. Today, KM’s research centers and production lines operate worldwide, aiming to establish these standards globally. Cleanrooms are where these products are ultimately used, and we believe that a thorough understanding of these spaces is essential to creating flawless products. This book marks KM’s first step in documenting that foundation. Just as we take care in crafting our products, this book was thoughtfully planned and written, with the hope that it will serve as a valuable resource in the field.

C E O



HEPA(High Efficiency Particulate Air) filters used in KM cleanrooms.
These filters are capable of removing at least 99.97% of fine particles with a diameter of 0.3μm.

THE BASICS OF A CLEANROOM

Q.1

What is
a cleanroom?

Q.2

What are the main sources
of contamination in
a cleanroom?

Q.3

How is contamination
in a cleanroom measured?

Q.4

What methods are used
for contamination control
in a cleanroom?

KM Story 1

Building expertise and
establishing a unique system
with steady dedication

A cleanroom is a controlled environment designed to prevent and manage the entry and generation of particles and microorganisms. It's essential for producing products that require ultra-precision, high purity, cleanliness, and sterile conditions.

Q.1 What is a cleanroom?

A cleanroom, or "clean space," is defined as an environment free from contaminants and particles. According to ISO 14644-1, established by the International Organization for Standardization(ISO), a cleanroom is a controlled environment where the concentration of airborne particles is regulated and classified based on particle size and quantity. It is specifically designed to minimize the introduction, generation, and retention of particles, maintaining a consistently high level of cleanliness(ISO 14644-1:2015-Cleanrooms and associated controlled environments, 2015). Cleanrooms are essential in industries such as semiconductors, display manufacturing, pharmaceuticals, food production, and aerospace, where ultra-precision, high purity, cleanliness, and sterile conditions are crucial. Even slight contamination from dust or particles can greatly impact product quality, and the use of cleanrooms, along with proof of their effectiveness, has become a standard for validating product quality across these sectors.

Cleanrooms are generally classified into two main types: Industrial Cleanrooms(ICR), which control particle contaminants, and Biological Cleanrooms(BCR), which manage biological contaminants. Each type is rated by a cleanliness "Class" level based on the concentration and size of particles within a cubic meter of air.

The ISO 14644 standard, established by the International Organization for Standardization, is the primary global standard for cleanroom cleanliness. Other standards influencing industry practices include the U.S. Federal Standard(FED-STD-209E,

Q.1

used until 2001), the Korean Standard(KS I ISO 14644-1), the Japanese Standard(JIS B 9920), the British Standard(CBS5295-1), and the German Engineering Federation Standard(VDI 2083). NASA's standard(NASA NHB 5340.2) is also frequently referenced for biological cleanrooms.

The ISO 14644 standard classifies cleanroom air cleanliness by the number of particles of 0.1μm or larger per 1m³. For example, a room with 10 or fewer particles larger than 0.1μm meets ISO Class 1, while a room with 100 or fewer particles meets ISO Class 2. Cleanliness requirements vary by industry: automotive parts factories and surgical rooms typically need ISO Classes 5-6; pharmaceutical and food production facilities require ISO Classes 5-7; electronics precision component factories use ISO Classes 4-7; and semiconductor facilities require ISO Classes 4-6. Unlike ISO standards, which measure particles per 1m³ of air at 0.1μm or larger, the FED-STD-209E standard classifies cleanliness based on particles of 0.5μm or larger per 1ft³. Under FED-STD-209E, a space with one or fewer particles larger than 0.5μm is classified as Class 1; space with 100 particles or fewer is Class 100; and space with 1,000 particles or fewer is Class 1,000. For comparison, typical outdoor air would be around Class 3,000,000, and indoor air about Class 500,000 under FED-STD-209E, highlighting the extreme cleanliness of cleanrooms. Although FED-STD-209E was officially withdrawn in 2001, it continues to be widely referenced globally.

<Cleanliness Standard Comparison(FED-STD-209E, ISO 14644)>

Standard	Previous Cleanliness Standard (FED-STD-209E)	Current Cleanliness Standard (ISO 14644)
Unit Volume	$1ft^3(0.028m^3)$	$1m^3$
Classification	Classification is determined by the number of particles ≥0.5μm per 1ft³	Classification is determined by the number of particles ≥0.1μm per m³
Example	A concentration of 100 particles ≥0.5μm per 1ft³ corresponds to Class 100	A concentration of 1,000 particles ≥0.1μm per m³ corresponds to ISO Cleanliness Class 3(10³)

<ISO 14644 Cleanliness Classifications>

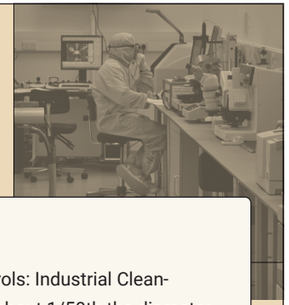
ISO Cleanliness Class	Allowable Particle Concentration(particles/m³) for Particles of Specified Size or Larger						Reference FED-STD-209E Standards
	0.1μm	0.2μm	0.3μm	0.5μm	0.1μm	5μm	
1	10	2	-	-	-	-	
2	100	24	10	4	-	-	
3	1,000	237	102	35	8	-	1
4	10,000	2,370	1,020	352	83	-	10
5	100,000	23,700	10,200	3,520	832	29	100
6	1,000,000	237,000	102,000	35,200	8,320	293	1,000
7	-	-		352,000	83,200	2,930	10,000
8	-	-		3,520,000	832,000	29,300	100,000
9	-	-		35,200,000	8,320,000	293,000	1,000,000

Q.1

<Class Standards by Industry>

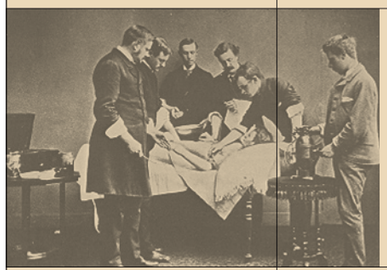
Industry	Application Areas	Class(ISO Standard) Unit: particles/1m³					
		3	4	5	6	7	8
Medicine, Pharmaceutical Research Institutes, Film Manufacturing	Pharmaceutical Manufacturing Plants			■	■	■	
	Laboratory Animal Housing, Photographic Sensitizer Manufacturing	■	■	■	■	■	
Electrical and Electronic Equipment	Semiconductor Devices, Integrated Circuits, Liquid Crystal Panels, VTRs, Computer Tapes		■	■	■		
	Computer Manufacturing Processes, Computer Operation Rooms			■	■	■	
Precision Machinery Processing	Precision Gyroscopes, Bearings, Optical Lenses, Electrical Contacts, Precision Guidance Devices, Precision Fluid Components		■	■			
	Small Instruments, Hydraulic Control Devices, Bearings, Fluid Components			■	■	■	
	Watches, Cameras, Actuators, Oxygen, Liquid Oxygen Pumps			■	■	■	■
	Viscose Process, Vinyl Sheets, Synthetic Paper, Artificial Leather						■
Food	Enzymes, Breweries			■	■	■	■
	Production of Other Beverages, Pastry Manufacturing			■	■	■	
Hospital	Operating Rooms, Neonatal Units, Isolation Wards, I.C.U			■	■		
Ceramics	Precision Ceramics				■	■	
Printing	Precision Printing Plates, Electronic Printing Plates			■	■	■	
Synthetic Resins and Rubber	Artificial Heart Manufacturing, Pharmaceutical Containers, Surgical Gloves, High-Grade Latex			■	■	■	

Q.1 [1]



What are the differences between cleanrooms across industries?

Cleanrooms are generally divided into two main types based on their contamination controls: Industrial Cleanrooms(ICR), which focus on particle contaminants(targeting particles smaller than 1μm, about 1/50th the diameter of a human hair), and Biological Cleanrooms(BCR), which emphasize controlling microbial contaminants.
Industrial cleanrooms are essential in semiconductor and display manufacturing facilities, known as fabs. In these settings, particles on the surfaces of wafers or display layers, which consist of intricate electronic circuits and thin films, can lead to product defects, making particle control critical. Airborne particles may enter through workers or products and can also originate from equipment. To maintain a high standard of cleanliness, workers' clothing is cleaned before entry, and a specialized air system ventilates the space periodically. Temperature, humidity, pressure, airflow, noise, and vibration are also controlled to create a stable and clean environment.
In contrast, biological cleanrooms are designed to prevent the creation, growth, and spread of microorganisms. Since living microbes continuously grow and reproduce, they can lead to secondary contamination, requiring strict control of microbial concentrations to prevent risks.



Q.1 [2]

When were cleanrooms first developed?

The history of cleanrooms dates back to the 19th century, following the discovery of bacteria, which highlighted the need for contamination-free environments. By the 20th century, with the advancement of industrialization, the demand for clean spaces became more specific. During World War II, it was discovered that dust on machine and electronic components was a primary cause of aircraft malfunctions. This finding led the U.S. Department of Defense to initiate research on cleanrooms, which then spread to various industries, spurring cleanroom technology development. The modern cleanroom, designed to control particles and filter air, was first created by American physicist Willis Whitfield. The first U.S. Federal Standard for cleanrooms, Federal Standard 209(FED-STD-209), was introduced in December 1963 and was later revised several times: FED-STD-209A in 1966, 209B in 1973, 209C in 1987, 209D in 1988, and finally 209E in 1992. However, on November 29, 2001, FED-STD-209E was officially withdrawn based on a recommendation from an IEST working group, and the ISO 14644 standard from the International Organization for Standardization(ISO) has since become the global standard(as of 2024).

Q.2 What are the main sources of contamination in a cleanroom?

The primary sources of contamination are particles and microorganisms, which can come from personnel, materials, equipment, facilities, maintenance activities, and air.

Workers, essential to cleanroom operations, paradoxically often become the primary source of contamination. Contaminants from their bodies—such as skin flakes, sweat, hair, and fibers from clothing—can all introduce particles into the environment. Everyday movements like speaking, coughing, or even slight gestures can release particles of varying sizes. Just standing up or sitting down can release up to 100,000particles(0.3μm or larger per minute), while walking at a moderate pace(5.7km/hr) can release around 7.5million particles. Notably, particles can carry other contaminants, including microorganisms, depending on their size. Statistics show that 60–75% of product defects can be attributed to human factors, making it essential for workers to enter cleanrooms with a commitment to preventing particle contamination.

Choosing the right equipment and using it properly is crucial to this effort. Workers should select cleanroom clothing appropriate for their work and ensure it is worn and maintained correctly. Hair cover and hood must fully cover hair and eyebrows, and gloves should be worn to avoid gaps at the wrists. Knitwear like sweaters, which shed more particles, is prohibited in cleanrooms, and all clothing worn under cleanroom garments must be strictly controlled to maintain cleanliness. In addition to workers, equipment and facilities also contribute to contamination. Particles can be released from cleanroom walls, floors, and ceilings, as well as from anti-static coatings and paints. Damaged or worn surfaces can shed particles, requiring regular inspections. Materials used in processing, assem-

bly, and packaging, such as adhesives, lubricants, and water, can also introduce particles and microorganisms, making it important to check for impurities.

Maintenance, repairs, and cleaning must follow strict procedures, and the cleaning tools themselves require careful hygiene management. Residual particles or standing water left after cleaning can allow microorganisms to proliferate, so thorough final checks are essential. Proper ventilation of contaminated air is another critical factor in maintaining cleanroom standards. If the performance of the air circulation system filters(such as HEPA or ULPA) decreases, contaminants may not be fully removed, and improper airflow can lead to the buildup of pollutants in certain areas. Microorganisms also enter cleanrooms through various pathways: they can come from bacteria, mold, workers' respiratory systems, or even small insects that find their way inside. Tiny particles from seemingly insignificant sources can significantly impact cleanroom cleanliness. Maintaining a "clean" cleanroom requires more effort and precision than might initially be expected. Km

<Particle Generation by Motion(Particles ≥ 0.3μm, count/min)>

Movement	Particle Generation
No Movement (Standing or Sitting)	100,000
Light Movement of Head, Hands, and Arms(Sitting)	500,000
Moderate Movement of Body and Arms, Tapping Floor with Toes(Sitting)	1,000,000
Motion of Rising from a Sitting Position	2,500,000
Slow Walking 3.2km/hr	5,000,000
Normal Walking 5.7km/hr	7,500,000
Fast Walking 8km/hr	10,000,000
Stair Climbing	10,000,000
Jumping Motion	15,000,000

Can static electricity be considered a source of contamination in cleanrooms?

The need for static control design and anti-static products in cleanrooms is becoming increasingly critical. When static electricity is generated, charges accumulate on surfaces, attracting airborne particles. This particle attraction poses serious issues for high-precision products like semiconductors, where even slight contamination can lead to major defects. Static charges can also cause malfunctions in sensitive equipment, impacting the overall efficiency of the production line. Static electricity occurs when two materials of different properties come into contact and then separate. It can be triggered by several factors, including material type, surface conditions, ambient humidity, contact pressure, and separation speed. Static can also arise from worker movements or from contact between their clothing and equipment. In cleanrooms that use chemical substances, controlling static is even more essential, as some volatile organic compounds(VOCs) are especially sensitive to static and easily become charged. Charged chemicals can react with other substances in the cleanroom or lead to contamination. Preventing static electricity begins with educating workers on its causes and control methods to build awareness of effective static prevention.

The following measures can further help prevent and control static:

- Use anti-static materials for work surfaces, floors, equipment, and clothing, and maintain surface resistance values according to set specifications to minimize static generation.
- Since static electricity is more likely to occur in low humidity, keep the cleanroom at an appropriate humidity level to reduce static buildup.
- Ground all work surfaces and equipment, and have workers use grounding mats or wear grounding wrist straps to prevent static accumulation.
- Install ionizers in the cleanroom to neutralize airborne charges, and place ion blowers near workstations to eliminate static in work areas.

Q.3 How is contamination in a cleanroom measured?

Cleanroom contamination is typically evaluated based on the levels of airborne particles, microbial contamination, surface contamination, and VOC concentration, with various instruments used to measure these indicators.

In a cleanroom, where a meticulously refined environment is crucial, any contamination can directly impact product quality and lead to defects. This makes it essential to identify sources of contamination, assess their effects, and understand the characteristics and concentrations of contaminants. To create a space where even a single speck of dust is unacceptable, the cleanroom environment must be rigorously evaluated and managed with various measurement technologies. Below is an introduction to essential contamination measurement equipment used to maintain the ultra-clean environment in cleanrooms.

Laser Particle Counter

In clean air, particles travel in straight lines, but when encountering dust, they scatter. This scattering property of lasers is used to measure the size and quantity of airborne particles. Air is sampled at various locations in the cleanroom over a set

<KM's Contamination Measurement Method>

KM utilizes multiple TSI 9110 models, a recognized standard in particle measurement, for regular contamination assessments. This laser particle counter model complies with ISO 21501-4 standards(light-scattering particle counters for cleanrooms) and can measure particle sizes and distributions in the 0.1–10μm range, making it ideal for assessing ISO cleanliness classes 1 and 2.

Q.3

period, and particles are measured as they pass through a laser beam. The number of dust particles is determined by counting scattering events, and their size is calculated based on the amount of scattered light. These results help evaluate the cleanroom's cleanliness class.

Air Sampler

This device monitors airborne microorganisms by collecting and concentrating air samples. Air samples are taken from various cleanroom locations and inoculated onto culture media, where they are incubated for a specified period. The number and types of microorganisms are then analyzed to assess the microbial contamination level in the air.

Swab Test

This method evaluates the cleanliness of surfaces within the cleanroom. A swab collects contaminants from surfaces, and the sample is analyzed to determine the degree of particulate or microbial contamination present.

Contact Plate

A culture media plate is pressed onto surfaces for a set time to collect microorganisms. After incubation, microbial growth can be observed, and the number and types of microorganisms are analyzed to evaluate surface microbial contamination levels.

Volatile Organic Compound(VOC) Detector

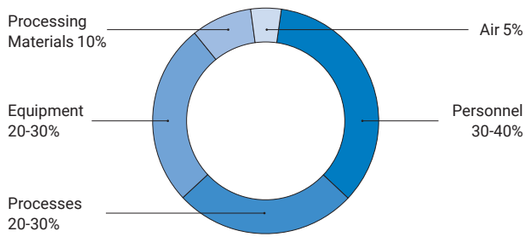
This device measures VOC levels in indoor air resulting from cleanroom disinfection. Residual VOCs from disinfectants can lower product quality and, at certain concentrations, can impact worker health. Air samples from various cleanroom locations are collected and analyzed with a VOC detector to measure the concentration of chemical substances in the air.

Adsorbent Sampler

This device assesses the concentration of chemical contaminants in the cleanroom. Using a sampler that adsorbs specific chemicals, contaminants are collected, and the sample is analyzed to measure the concentration of chemical pollutants.

In industries with advanced manufacturing processes, cleanliness control is essential for ensuring product quality. In sectors like semiconductor and precision manufacturing, the increasing miniaturization of processes makes contaminants in cleanrooms increasingly impactful.
Regularly measuring contamination levels within the cleanroom and building a database are critical for efficient cleanroom operations and quality assurance. Long-term data analysis allows for monitoring contamination trends, facilitating prevention, countermeasure development, and swift responses to abnormalities. Companies operating cleanrooms are advised to prepare and maintain an Environmental Monitoring Procedure document. Measuring and analyzing contaminants in a cleanroom is the foundation of reliable cleanroom management. KM

<Cleanroom Contamination Contribution>



Q.3 1

How extensive should the measurement locations for contamination monitoring equipment be, and how frequently should contamination measurement and analysis be conducted?

For particle measurement with laser particle counters and airborne microorganism monitoring with air samplers, measurement locations can be broadly applied across work areas within the cleanroom, as well as at air purification system inlets and outlets, walls, floors, and ceilings.
The frequency of contamination measurement and analysis should be based on the cleanroom's operational conditions and management requirements, with adherence to relevant standards and regulations. The measurement interval varies depending on the cleanliness class of the cleanroom, with more frequent testing required for higher cleanliness levels. ISO 14644 certification specifies an annual minimum for measurements but recommends adjusting the testing frequency as needed based on regular monitoring results. Typically, monthly testing or more frequent intervals are recommended.

Q.4

What methods are used for contamination control in a cleanroom?

Contaminants in cleanrooms can originate from personnel, processes, facilities, and equipment. To prevent quality degradation, it is essential to manage and control invisible contaminants, maintaining a consistent level of cleanliness in these environments. First, particle control is achieved through filter systems and air purification equipment, ensuring stability and quality in precise manufacturing processes. Additionally, personnel follow strict protocols and wear specialized protective equipment to minimize contamination in cleanrooms.

Air Management

HEPA and ULPA Filters | Filters are fundamental for maintaining high cleanliness standards in cleanrooms, supplying large volumes of air with contaminants effectively removed. High-Efficiency Particulate Air(HEPA) filters are the primary filters used in cleanroom systems, removing 99.95–99.97% of particles as small as 0.3μm. For environments requiring even stricter cleanliness, Ultra Low Particulate Air(ULPA) filters are used, capturing particles as small as 0.12μm with 99.99% efficiency and providing a higher filtration level than HEPA filters. Both types of filters should be replaced every 6–12 months.

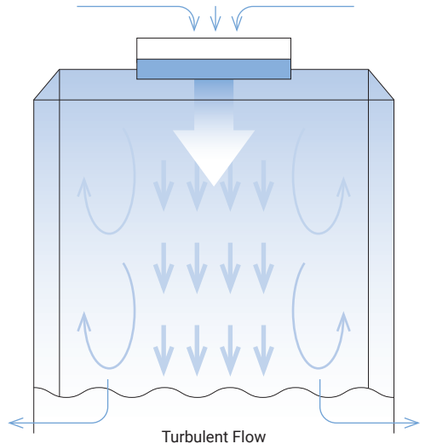
Laminar and Turbulent Flow | Airflow control is another effective method to minimize contamination. Laminar flow ensures that air moves uniformly in a single direction, preventing contaminants from accumulating in specific areas, while turbulent flow effectively removes airborne particles by mixing the air. Together, these airflow methods help maintain cleanroom standards.

Positive and Negative Pressure Maintenance
In cleanrooms for semiconductor manufacturing, precision engineering, and pharmaceutical production, positive or negative pressure systems are applied based on air pressure needs. Positive pressure maintains internal pressure higher than external levels, preventing external contaminants from entering by causing air to flow outward when

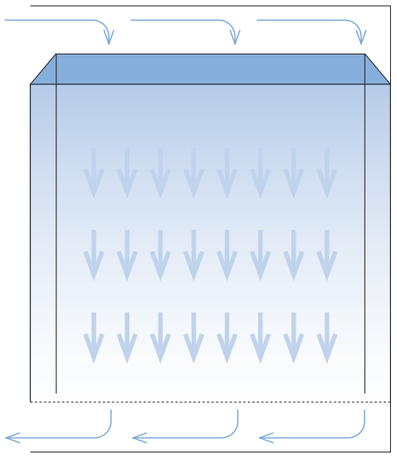
Advanced contamination control methods are applied in cleanrooms, including air management with high-efficiency filters, to keep contamination to a minimum.

Q.4

<Indoor Airflow Patterns (Turbulent Flow, Laminar Flow)>



Turbulent Flow



Laminar Flow(Unidirectional Airflow)

doors are opened. This method is commonly used in semiconductor and IT cleanrooms. Conversely, negative pressure keeps internal pressure lower than surrounding areas to contain contaminants, essential in medical and pharmaceutical cleanrooms(e.g., those used for penicillin manufacturing) where contaminants must not escape.

Personnel Management

Cleanrooms can be contaminated by particles and microorganisms emitted by personnel, so regular training on cleanroom protocols and contamination control is essential. Emphasizing personal hygiene is crucial, as contaminants from personnel can be contained through protective equipment. Specialized clothing—such as coverall, hood, shoes, hair cover, mask, and gloves—must be worn to prevent particle release, and these should be donned correctly to prevent contamination. Air showers are used to remove dust and contaminants from personnel and items upon entering, with strict access control to ensure only authorized individuals and items enter.

Using tools and equipment specifically designed for cleanrooms and regularly cleaning and inspecting them helps minimize contamination. Materials must also be carefully managed. Materials brought into cleanrooms should be pre-cleaned to remove contaminants, and their packaging should be kept clean. Chemicals must be stored in designated areas to prevent leaks or contamination.

Regular cleaning of cleanroom floors, walls, ceilings, and equipment must follow strict procedures. Periodic inspections and maintenance of the cleanroom's HVAC system, filters, and equipment are essential. Additionally, cleaning and maintenance activities should be meticulously recorded to enable future issue tracing if needed. KM

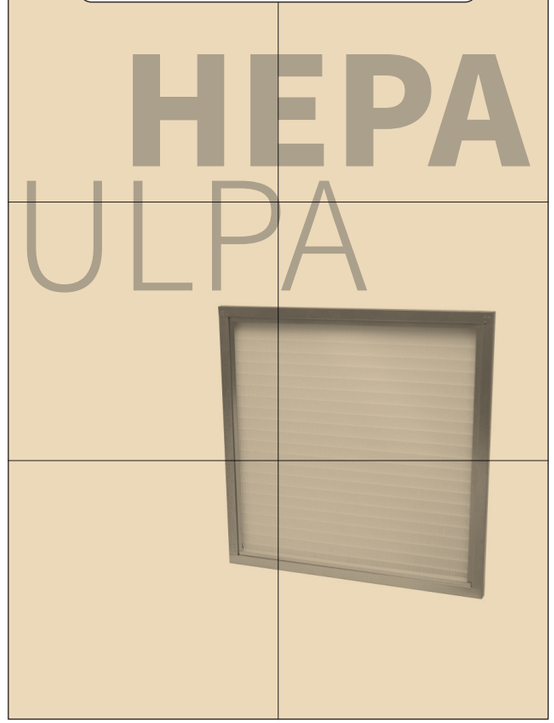
<Positive Pressure Methods and Cleanroom Classification by Class>

Classification by Indoor Cleanliness Standards (Typically based on particles ≥ 0.1μm)	**ISO 4** **ISO 5** **ISO 6** **ISO 7** **ISO 8** *Refer to Cleanroom Standards
Classification by Airflow Patterns	Laminar Flow Turbulent Flow
Classification by Controlled Targets	**Industrial Cleanroom(ICR)** Designed to control airborne particulate matter **Biological Cleanroom(BCR)** Designed to control biological particles
Other Standards	**GMP(Good Manufacturing Practice)** Guidelines for the manufacturing and quality control of pharmaceuticals, cosmetics, and food **GLP(Good Laboratory Practice)** Standards for the care, quarantine, and use of laboratory animals **Bio Hazard** Maintains negative indoor pressure to prevent contamination from spreading outside

Q.4 [1]

Do contamination control methods differ by cleanroom class?

Yes, contamination control methods vary by cleanroom class. Lower cleanroom class numbers indicate higher cleanliness levels, allowing smaller and fewer particles. To meet the particle concentration standards defined for each class, specific measures are required. Ultra-clean cleanrooms with lower class numbers rely on high-efficiency HEPA and ULPA filters, which capture particles with a high filtration rate. The type of internal airflow also varies: turbulent flow is used in ISO 6 to 8, vertical laminar flow is used in industrial cleanrooms of ISO 3 to 5, and horizontal laminar flow is employed in ISO 5 bio-cleanrooms.



KM Story 1

Building expertise and establishing a unique system with steady dedication

Bong-kyu Kim, KM Quality Team Manager

Could you briefly introduce yourself?

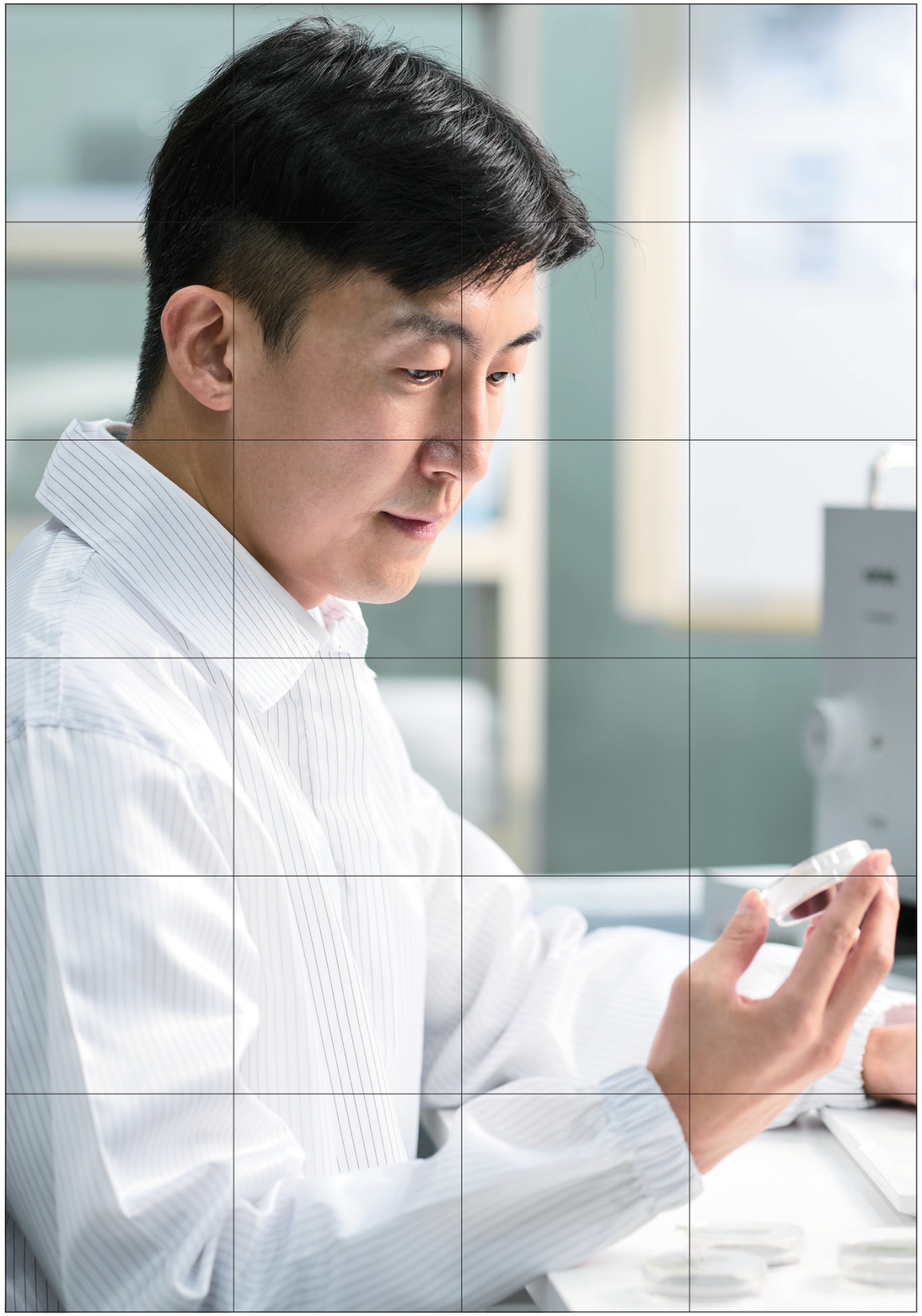
I joined KM on March 4, 2010, and I've been with the company ever since—over 14 years now. I'm part of the Quality Management Team, overseeing quality control for all products manufactured at KM. Most analyses for new product development and improvements are handled by the Quality Management Team.

Quality Management involves identifying areas for improvement and making updates, so the approach must be forward-thinking.

It's a mix. Quality management requires adherence to specific standards, so while improvements are made, they need to align with established guidelines, which sometimes calls for a conservative approach.

What have been some of the most memorable moments at KM?

One standout memory was during my initial training. We toured the Pyeongchang plant's PVC glove line, my first-ever experience in a cleanroom. Watching the line operate non-stop as workers carefully removed gloves from molds and stacked them was incredibly impactful. That scene of an orderly, tireless production line left a strong impression of KM's dedication. That plant eventually became the foundation for later expansions, like the Anseong plant, making it feel like witnessing a critical milestone.



KM Story 1

What project have you recently been focused on?

A recent project involved obtaining U.S. FDA 510(k)* certification for a KM product—our Tyvek pouch, a sterilized packaging material for cleanroom garments and medical devices. FDA certification, especially for medical devices, is known for its rigor. While we worked with a consulting firm, our team handled all documentation, analysis, and testing independently. KM is likely the first in the cleanroom consumables industry to apply for this certification. We also conducted biocompatibility and microbial barrier tests for the first time, which can cost close to $90,000 USD. Without strong company support, this would have been challenging. We recently completed the process and received the certification.

*** U.S. FDA 510(k)** | A certification for medical devices by the U.S. FDA, requiring extensive evaluation of product verification, data integrity, manufacturing processes, and safety, proving substantial equivalence to a legally marketed device and allowing sales within the U.S.

Pursuing certification seems to reflect KM's emphasis on quality.

Absolutely. KM holds certifications like GRS** and the highest domestic medical device Class 1 certification. We likely have the most certifications in our industry.

**** GRS Certification** | Certifies the use of recycled materials in textiles and apparel, covering each step from material collection through processing, production, and sales, ensuring continuous management.

What cleanroom levels are operated by KM?

KM operates cleanrooms in Korea, China and Vietnam across various classes, including ISO 4, 5, 6, 7 and 8. We first introduced cleanrooms with the completion of the PVC glove line in 1990, and high-class cleanroom maintenance began with the ISO 4 Wiper Line in 1996.

Controlling contamination and maintaining the environment are crucial in cleanrooms. How does KM manage this?

We begin by designing and configuring each cleanroom to meet specific product quality requirements, ensuring the correct filters and airflow control. Since personnel are a major source of contamination, we enforce strict entry protocols and attire regulations.

Garment laundering and replacement cycles are carefully managed based on the work's nature. To maintain cleanliness, we monitor cleanroom performance and conduct scheduled cleaning. Air particles and differential pressure are measured every two weeks, and temperature and humidity daily. We verify key parameters like filter airflow, illumination, and noise twice a year. Dedicated personnel oversee all environmental measurements, including daily cleaning of work tables, quarterly wall cleaning, and semi-annual ceiling cleaning. We also implement annual training plans, using cleanroom resources for thorough education.

What areas will KM focus on moving forward?

We're building systems to meet pharmaceutical and biotech client requirements, such as microbial control and GMP certification. Stabilizing the quality system at our Vietnam plant is also a top priority. Our Quality Management Team is the largest within KM, reflecting the pride and effort we place on quality. We aim for KM to remain recognized as the leader in cleanroom and clean product management.

Nano-max RC fabric, made from recycled PET bottles(RE PET)

CLEANROOM OPERATION & MANAGEMENT

Q.5

What preparations are required to enter a cleanroom?

Q.6

How should cleanroom garment be chosen?

KM Story 2

A Journey toward a perfect Eco-Friendly cycle

Q.7

How should cleanroom garment be managed?

Q.8

How should cleanroom supplies be selected?

Q.9

How should a cleanroom be maintained and managed?

Q.10

What tests are required for ISO 14644 certification of a cleanroom?

Q.5 What preparations are required to enter a cleanroom?

Before entering a cleanroom, personnel must go through a preparation area between the general zone(contaminated area) and the cleanroom(clean zone) to ensure proper hygiene, garment and accessory following specific procedures.

Workers entering a cleanroom must take preparatory steps to prevent introducing or generating contaminants. This preparation includes hygiene management, garment management, and access control.

Hygiene management focuses on removing potential contamination sources. Before putting on cleanroom-specific garment, workers must wash their hands to remove even fine contaminants. Makeup, nail polish, and perfume are prohibited as they can generate particles, and jewelry that can trap dust is also not allowed.

After completing hygiene management, workers put on cleanroom-specific garment, including full-body coverings to prevent contaminants from hair, skin, or respiratory droplets from entering the environment. Required garment includes coverall, hood, hair cover, shoes, mask, and gloves. Gloves are washed with deionized/reverse osmosis(DI/RO) water or ethanol and dried using cleanroom-specific wipes or dryers, as towels can generate dust.

Once hygiene and garment are verified, workers proceed through the final entry procedures. This includes stepping on sticky mats at the cleanroom entrance to remove contaminants from shoe soles and then entering the air shower room, a chamber that blows high-speed air to dislodge contaminants from clothing and the body. Light movement is recommended for thorough air coverage.

When bringing equipment and supplies into the cleanroom, additional procedures are required.

Air Shower Room for Supplies

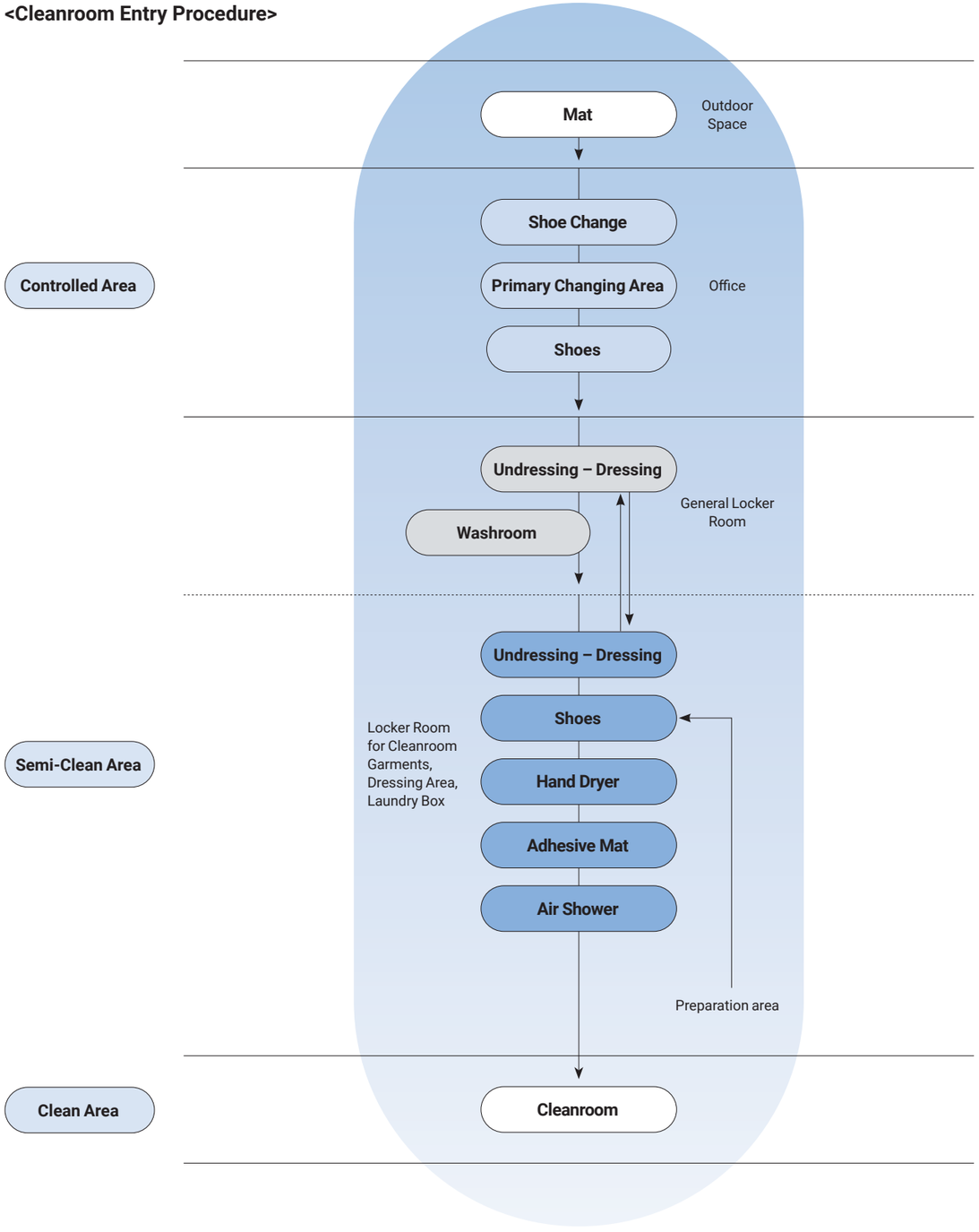
Supplies should be placed on a stainless steel(-SUS) cart to minimize dust, covered with static-dissipative fabric to prevent static buildup, and brought into the supply air shower room. Once the external door is fully closed, the internal door opens, allowing entry to the cleanroom.

Pass Box

For bringing in various consumables used within the cleanroom(such as packaging bags and wipes) or removing finished products, it is best to use a pass box with separate entry and exit doors to prevent cross-contamination. Km

Q.5

<Cleanroom Entry Procedure>



Q.5 1

How is the cleanliness level of the preparation room determined?

The preparation room is where personnel change into regulated garment and undergo initial contamination control before entering the cleanroom, making it a crucial space for managing cleanroom cleanliness.
The cleanliness level of the preparation room is set based on the cleanroom's grade. For example, if the cleanroom is ISO Class 5, the preparation room is typically set to ISO Class 6 or 7 to create a gradual transition. In lower-grade cleanrooms, personnel may remove both clothing and shoes in a single area, while in industries requiring higher cleanliness, changing and shoe removal areas are separated. Because the purpose of the preparation room can vary depending on the cleanroom's function, products, and operating conditions, each company selects the cleanliness level based on its specific requirements rather than a standardized benchmark.

Q.5 2

What items are required in the Preparation room

Clean Locker	A storage unit equipped with an FFU(Fan Filter Unit) to store cleanroom clothing in a clean condition.
Cabinet	Used for storing and disposing of accessories such as gloves, masks, and hair covers. Made of stainless steel or steel pipes for durability and space efficiency, functioning as both a storage unit and waste container.
Bench	Needed for changing garment.
Mirror	Used to check that cleanroom garment is properly worn after putting it on
Sticky Mat	A protective mat to remove contaminants from shoes or reduce static electricity before entering the cleanroom.
Handwashing (Sanitizing) Station and Dryer	For handwashing, sanitizing, and drying.
Manual	Essential guidelines posted on the wall.

Q.6

How should cleanroom garment be chosen?

Cleanroom garment includes coveralls, hood, shoes or shoe covers, gloves, masks, and hair cover. Proper garments should be selected according to environmental standards outlined in ISO 14644.

Cleanroom workers must follow dress codes appropriate for the work environment. Cleanroom garment should comply with relevant standards, such as the IEST-RP-CC003 document, or align with the company's internal cleanroom operation guidelines. Typical cleanroom garment includes coverall, innerwear, hood, shoes, gloves, masks, and hair cover.

Coverall

Cleanroom clothing varies according to the cleanroom's cleanliness grade and is available in one-piece suits, two-piece sets, or gown styles. In ISO Class 3–5 environments, full-coverage one-piece suits are worn, while in ISO Class 6–8 environments, two-piece suits or gowns over regular clothing are suitable.

These garments are usually made from fine polyester fibers, which prevent the release of dust, particles, and fibers and block fine particles or dust from passing through the tightly woven fabric. Cleanroom innerwear help reduce contamination from perspiration and improve comfort, often incorporating conductive fibers to prevent static.

Hood

Hoods are worn after putting on one-piece or two-piece suits to effectively block particles from the head and neck. Typically, hoods are used with one-piece suits, while caps are worn with two-piece sets. These hats are made from static-dissipative fabric to minimize static.

Q.6

Shoes

Shoes, specialized for contamination control, come in standard styles or as safety shoes with toe caps for foot protection. In cleanrooms where disposable options are required, such as sterile rooms, anti-slip shoe covers can be worn over cleanroom shoes. In cultures where shoe removal is uncommon, such as in the United States, overboots may be worn over regular shoes.

Gloves

Common glove materials in cleanrooms include PVC, nitrile, and latex, with specific gloves chosen based on the cleanliness grade. Cleanroom gloves control particles, ions, and surface resistance, and some companies also regulate glove thickness and tensile strength to prevent tearing.

PVC gloves are made from clean PVC material to minimize contaminants such as particles and ions.

Nitrile gloves are made from advanced synthetic nitrile to reduce skin allergies and include anti-static agents for ESD(Electro Static Discharge) properties, offering durability against tearing.

Latex gloves provide heat resistance, cost-effectiveness, and suitability for delicate tasks like electronics assembly.

Other options include seamless glove and neotril gloves. Prolonged glove use can cause eczema due to perspiration, making seamless gloves a suitable alternative; these gloves allow moisture to escape while blocking water ingress, helping prevent eczema. Seamless gloves also reduce contamination by eliminating needle holes.

Neotril gloves are recommended for chemical handling in cleanrooms due to their chemical resistance, using neoprene to prevent liquid organic compounds from being absorbed by the skin.

In ISO Class 6 environments, ESD gloves or anti-static PU-coated gloves are used for effective static control.

Accessories

In high-cleanliness cleanrooms such as ISO Class 3–5, additional accessories help minimize exposure. Hair covers are worn under hood or hat to prevent contamination from hair, and masks and goggles are used to cover the face. Some pharmaceutical lines also recommend cleanroom-specific socks.

The following are KM's internal dress code standards based on cleanroom environments, though each company may adapt these according to its product handling, processes, and contamination risk assessments.

ISO Cleanliness Class	7 / 8
FED-STD-209E	10,000 / 100,000
GMP GRADE	C / D

ISO Cleanliness Class	3 / 4 / 5 / 6
FED-STD-209E	1 / 10 / 100 / 1,000
GMP GRADE	A / B

Q.6

Q.6 1

What are the characteristics of different types of fabrics used in cleanroom?

Cleanroom clothing is typically made from microfibers like polyester, which generate minimal contaminants and are tightly woven to block fine particles or dust. Anti-static and durability properties are also standard features.
Additionally, fabrics with enhanced breathability, chemical resistance, and eco-friendly materials are being developed to improve worker comfort and safety. With the growing focus on ESG management, the demand for sustainable products is expected to rise.

Breathability | Nano-max™ cleanroom clothing features a lightweight, breathable fabric with specialized post-processing for excellent particle capture. This design prevents heat and sweat buildup, ensuring comfort during extended wear.

Chemical Resistance | Nano-chem™ cleanroom clothing uses a PTFE film coating on the outer layer to protect workers handling hazardous chemicals in cleanroom environments.

Eco-friendliness | Nano-max™ RC cleanroom clothing is made from recycled PET bottle yarn, a GRS-certified product created as part of Company A's ESG initiative.

Q.6 2

How are reusable and disposable items distinguished?

Typically, cleanroom clothing and shoes can be reused, with a validated cleaning schedule to determine their replacement cycle. However, accessories such as gloves and masks are single-use and must be discarded after each use.
In sterile cleanroom environments, replacement cycles for clothing are determined by both cleaning and sterilization validation*. In some sterile cleanrooms where reuse is not feasible, disposable garment sets made from nonwoven fabric are used.

***Validation** | refers to verifying and documenting that a specific process, method, or system consistently meets predefined standards.

KM Story 2

A Journey toward a perfect Eco-Friendly cycle

Yong-seok Joo, Sales Team Manager

Could you briefly introduce your work?

I work to understand and anticipate the needs of customers using KM products and discover new demands. This year marks my 21st with KM.

In your 21 years with KM, are there any experiences that stand out?

One memorable experience was supplying anti-static shoes to “A”, a leading global semiconductor company. Until 2021, anti-static shoes were one of the most challenging products for semiconductor customers. At that time, cleanroom shoes were designed with minimal support and basic air cushioning. Prolonged use led to discomfort and fatigue, and the lack of ventilation made them particularly uncomfortable in the summer.

KM identified these issues and set out to create a solution. Developing shoes that combined lightweight design, cushioning, and breathability was complex and came with a cost increase. Initially, the shoes were sold primarily to workers with foot issues or those working long hours in cleanrooms. But

within a year, word of mouth spread, and now KM's anti-static shoes, like the KMSF-19HB, hold a 95% market share at A. This experience taught me that users recognize quality first and reinforced my pride in KM products.

I understand KM also collaborated with Company A to develop anti-static garments.

Following the 2015 Paris Agreement, initiatives for carbon neutrality took off globally. With major clients in the semiconductor and display industries, KM anticipated issues like carbon taxes. As early as 2018, when terms like RE100*, Net Zero**, and GRS were still new, KM started researching anti-static garments for A. In 2020, A proposed an ESG project, leading to a joint development of these garments.

* **RE100** | A global initiative where companies commit to sourcing 100% of their electricity from renewable energy sources.

**__Net Zero__ | Achieving a balance between greenhouse gas(GHG) emissions produced and removed, resulting in zero net emissions.

Could you tell us about the garment development process?

We began development in 2020 and, by 2022, completed the Nano-max RC, the first anti-static garment in Korea made from RE PET. This was the result of three years of work. In collaboration with recycling and textile companies, we created Nano-max RC from recycled PET bottles. The process involved converting used PET bottles into high-purity recycled pellets, melting them to produce recycled yarn, and then using this yarn to make anti-static fabric. We tailored the fabric to meet A's semiconductor line specifications, considering factors like weight, thread thickness, air permeability, and comfort.

What are the key features of the Nano-max RC garment, designed specifically for semiconductor lines?

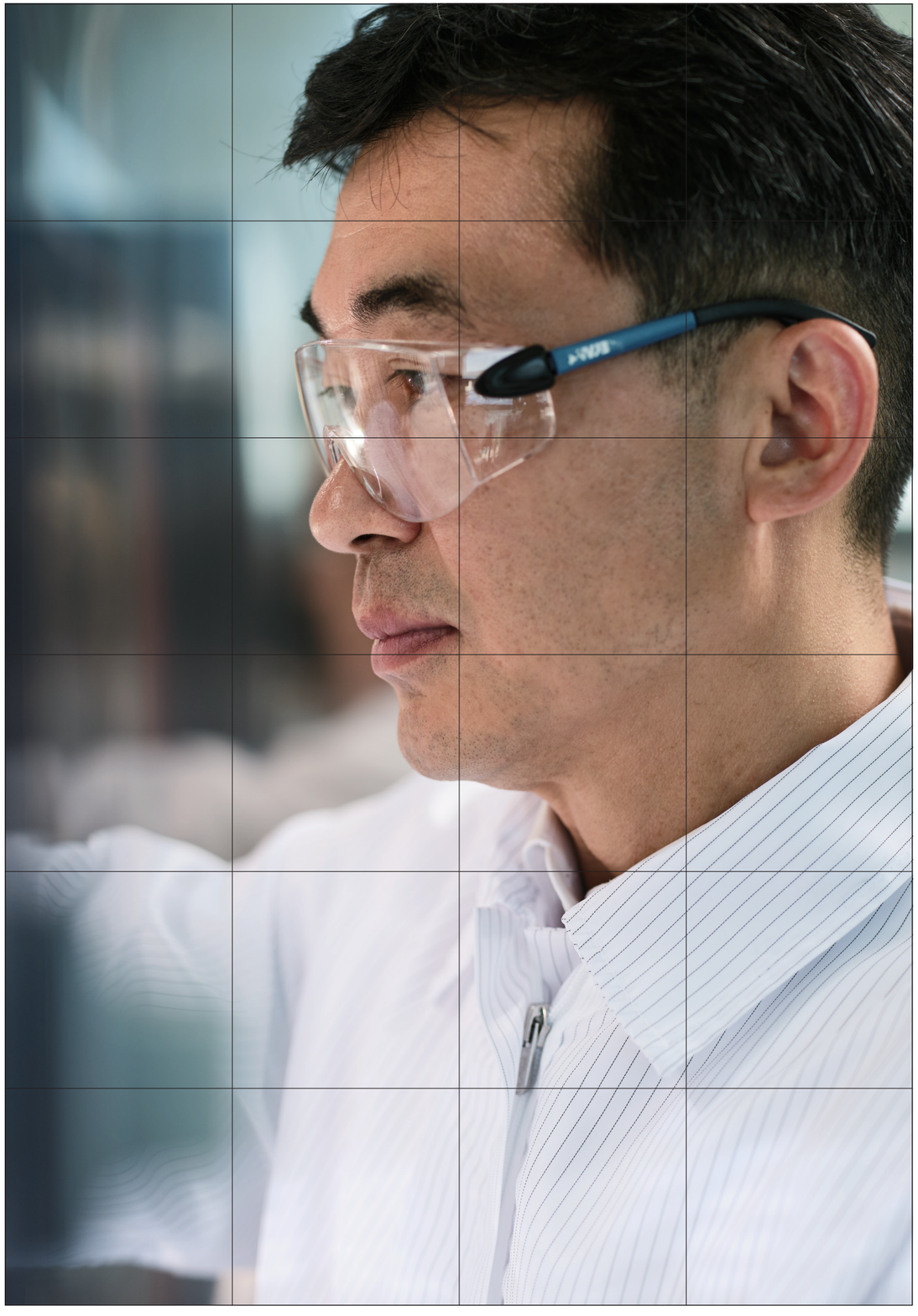
First, it's lightweight. Standard anti-static garments weigh over 530g each, while Nano-max RC weighs only 280g(XL size), reducing the weight by 47%. This reduction alleviates worker fatigue and improves mobility, enhancing productivity. Although the fabric is thinner, durability is not compromised; tensile strength increased by 30%, from 1,120 kgf/cm² to 1,470 kgf/cm². The fabric is also specially woven to provide privacy and prevent the exposure of foreign particles. Its particle capture efficiency for 0.1μm particles is 51.5%, a significant improvement over A's previous garments, which had a 34.9% efficiency, making Nano-max RC ideal for high-cleanliness cleanrooms.

What environmental benefits are achieved by using the Nano-max RC garment made from recycled PET bottles?

Each Nano-max RC garment uses 220g of recycled PET, equivalent to about 20 500mL bottles. This process emits approximately 65% less carbon than producing new fibers from petroleum.

What projects are planned after Nano-max RC?

Although Nano-max RC is made from recycled PET, it cannot be recycled again due to the technical difficulty of separating the carbon conductive yarn. However, KM is researching ways to reuse recycled anti-static fabric. If we can eliminate incineration and achieve continuous reuse, we will have created a truly sustainable cycle. KM



Disposable garment and accessory should be discarded immediately after leaving the cleanroom, while reusable garment should be stored in designated areas with FFUs(Fan Filter Units) to maintain cleanliness and should be regularly washed by specialized services.

Q.7 How should cleanroom garment be managed?

Cleanroom garments are specialized clothing designed to minimize the entry, generation, and accumulation of particles within cleanrooms. Made from materials that prevent lint shedding and static generation, these garments include coverall, hood, hair cover, shoes, gloves, masks, and goggles. Some items are disposable, intended to be discarded immediately after use to prevent contamination, while others are designed to withstand cleaning, sterilization, or autoclaving, making them reusable. Reusable garments must be stored in a dedicated area within a preparation room equipped with a Fan Filter Unit(FFU) to maintain controlled temperature, humidity, and cleanliness. They should be laundered regularly according to a specified replacement cycle, and only through specialized cleanroom laundry services. Such services use special detergents and deionized water(DIW) to prevent fiber damage and maintain cleanliness. After washing, the garments are packaged within the cleanroom according to validated conditions, including specific times and cycles for rinsing, spinning, and drying.

Garments supplied to sterile cleanrooms undergo an additional post-wash step: they are sterilized in their packaging using gamma ray sterilization. This method is well-established for microbial control, reducing validation costs, and enabling faster product release. Prior to sterilization, a sterilization validation process is conducted, starting with a bioburden test to measure microbial contamination in the environment and samples to ensure effective sterilization. Additional validation steps include determining the appropriate gamma dosage and performing microbial tests. To reduce errors, garments are marked with indicator labels on the packaging that change color post-sterilization. Strict verification steps are essential to ensure efficient laundering of cleanroom garments, confirming that, after laundering, particle counts are within acceptable limits and that no residual contaminants remain.

Laundry validation includes three stages:

1. **Installation Qualification(IQ)**: Verifying the installation of equipment, such as washers and dryers.

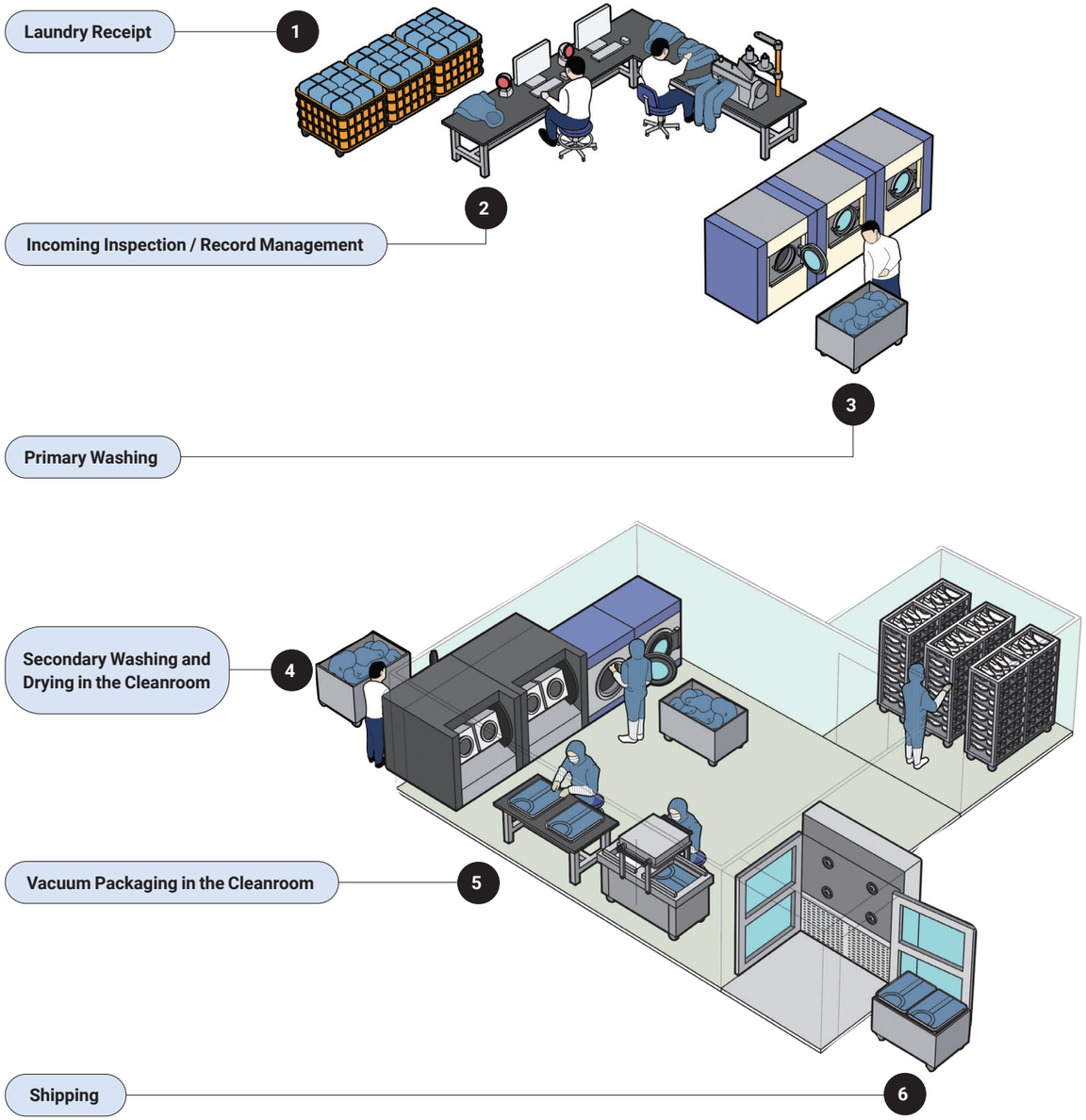
2. **Operational Qualification(OQ)**: Ensuring that washing and drying conditions are effective.

3. **Performance Qualification(PQ)**: Testing garments for particle count, durability, and contamination removal to ensure consistent results under specified conditions.

Due to the rigorous controls over collection, laundering, packaging, and delivery, it is essential to consult a specialized cleanroom laundry service to handle these garments properly. Km

Q.7

<KM Laundry Process>



<KM Cleanroom Laundry Solution Features>

Certified Processes and Professional Laundry Service

We operate and manage a specialized laundry program for localized contamination and odor removal, certified to ISO 9001, 14001, and 45001 standards.

Particle Testing and Reporting

Each part of the laundry process undergoes particle testing, with detailed reports provided to ensure expert contamination control.

Data Management with Barcoding

Each garment is assigned a barcode label, allowing for digital tracking of washing frequency.

<KM Cleanroom Laundry Differentiators>

Specially Formulated Detergent

In partnership with a detergent specialist, we use a custom-developed detergent that enhances the efficiency of particle and odor removal.

High-Temperature Washing

We offer a high-temperature washing program tailored to clients with specific odor control needs.

Modular Laundry Separation

Garments are washed in separate modules to maximize laundry efficiency and optimize energy use.

Q.7 1

How often should dust-proof clothing be washed?

The washing frequency for cleanroom clothing depends on the environment in which it is worn and the quality requirements of the manufactured products. For example, in pharmaceutical standards, A zones(ISO 5) require washing after each use, while C zones(ISO 8) generally require weekly washing, with adjustments based on cleanliness standards. For sterile garments, it is standard to wash after each use. It is recommended to evaluate the impact on product quality through a risk assessment and establish washing frequency based on internal verification and management.

Q.7 2

What is the maximum number of washes for cleanroom clothing?

The maximum number of washes for cleanroom clothing is closely tied to the garment's durability and should be managed according to the wearing environment. KM's internal durability tests indicate that after approximately 30 washes, a significant change in quality occurs. Setting washing frequency based on an internal risk assessment is recommended to ensure garment longevity and performance.

Q.8

How should cleanroom supplies be selected?

Cleanroom supplies should be made from materials and finishes that minimize particle generation. Anti-static materials or supplies with ESD functions should also be used to prevent particles from adhering due to static electricity.

Since cleanrooms are typically part of manufacturing facilities, various items essential for processes must be brought inside. Additionally, actions such as attaching, removing, pulling, and folding are often necessary in manufacturing but can generate particles, potentially leading to contamination. Therefore, all items used in the cleanroom—including paper and labels for documentation, bags and tape for packaging, carts for transporting items, and work tables and chairs—must meet standards to minimize particle generation. To prevent contamination from static attraction, items should also be made from anti-static materials or have ESD(Electrostatic Discharge) features to maintain the cleanroom's cleanliness.

Q.8

Clean Paper
Specially processed from selected pulp during production to reduce particle and static generation. It has excellent ink absorbency, preventing smudging and related contamination.

Clean Security Paper
A lint-free paper with anti-leakage features for security. A fine wire detectable by security devices is embedded in the paper, and the paper is color-coded for enhanced security.

Clean Label
Made from clean paper with a special adhesive that allows for easy removal without leaving residues, even after prolonged use, helping prevent contamination. Can also be used for product identification, tracking, and barcodes.

Clean PE Bag
Produced from pure PE resin without additives. A pre-treatment process removes impurities, generating no particles. Production from extrusion to packaging is performed in a cleanroom, ensuring safety.

Moisture Barrier Bag
A five-layer bag designed for storing moisture- and static-sensitive electronic components. Its multi-layer structure—anti-static coating+PET/nylon+aluminum+LDPE+anti-static coating—completely blocks moisture and protects contents from static.

Steam Bag
A sterilization-specific bag commonly used in the pharmaceutical, medical device, laboratory, and research industries. It includes an easy-tear feature to prevent particle generation when opening the bag.

Clean Tape
Tape made from PE film coated with a special adhesive that can be removed without residue, even after extended use, preventing contamination. The tape's excellent tensile strength prevents breakage.

Cart
A stainless steel cart designed to prevent contamination from corrosion or damage. The wheels are made from wear-resistant urethane to minimize particle generation during transport.

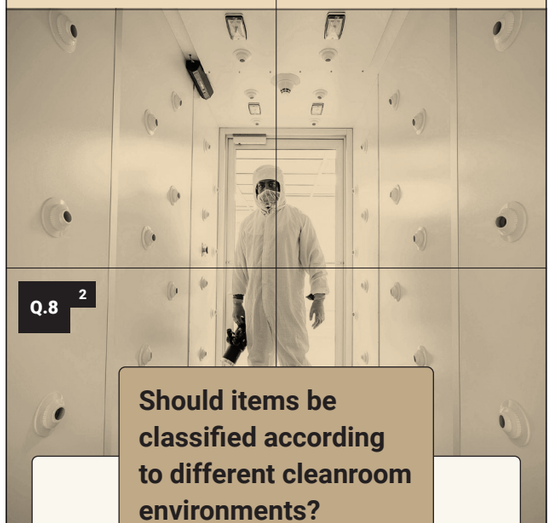
Work Table
A table with a perforated top to allow particles to fall through, reducing contamination. Made from stainless steel to prevent contamination from corrosion or damage.

Clean Chair
An aluminum die-cast chair with no welded parts, reducing contamination from corrosion or damage. Equipped with an Earth Chain to control static.

Q.8 1

Are there guidelines for bringing items into a cleanroom?

Yes, items must pass through decontamination areas, similar to personnel, and enter through either a pass box or an air shower room. The pass box is smaller, designed specifically for items, and prevents contaminated air from entering the cleanroom. It has a double-door system, with inner and outer doors that cannot open simultaneously.
The air shower room, primarily used for decontaminating personnel, can also be used for items. Cleanroom-specific items are first loaded onto a stainless steel cart to minimize particle generation, then covered with an anti-static fabric and placed in the air shower room. Once the outer door is fully closed and the inner door opens, the cart can enter the cleanroom. The double-door design prevents cleanroom and external air from mixing.



Q.8 2

Should items be classified according to different cleanroom environments?

No, as long as items are designated for cleanroom use, they can be used in any cleanroom environment.

Q.9 How should a cleanroom be maintained and managed?

Maintaining a cleanroom involves four essential principles: preventing particle entry, controlling particle generation, avoiding particle accumulation, and promptly removing contaminants. These principles focus on effectively removing contamination or preventing it from occurring in the first place.

To maintain cleanroom cleanliness, it is essential to regularly inspect equipment, monitor the environment, and document these activities for thorough management. However, the most crucial task is actively removing contaminants that accumulate within the cleanroom. Regular cleaning of equipment, work surfaces, floors, walls, and ceilings is necessary to prevent particles from impacting product yields, as fine particles from personnel movements, equipment, and facilities can gradually build up over time.

Wipers are essential for cleanroom cleaning. Designed to effectively remove particles, microbes, and residues, cleanroom-specific wipers are produced in controlled environments to ensure maximum cleanliness. They are used in a variety of applications, from wiping semiconductor glass to absorbing moisture on factory floors, and are often used with biocides, sporicides, or alcohol-based chemicals like ethanol and IPA. Cleanroom wipers are mainly divided into Dry Wipers and Specialty Wipers, with specific types as follows:

Q.9

Dry Wiper

Nonwoven Wiper

Made from nonwoven material, these wipers are highly absorbent and cost-effective, making them one of the most economical options. However, due to some particle generation from cut edges, they are typically used in lower cleanliness classes, such as ISO Class 6–8.

Polyester Wiper

These wipers are highly durable and generate minimal particles, making them ideal for use in cleanrooms. For higher cleanliness classes, such as ISO Class 3–5, they can be optimized with hot wire, laser, or ultrasonic cutting to minimize residue, followed by a washing process. When higher absorbency is needed, the polyester fabric can be double-layered through ultrasonic processing, producing a Double-Knit Wiper with three times the absorbency of a single layer.

Micro-denier Wiper

Made from a blend of polyester and nylon, these microfiber wipers offer exceptional absorbency and cleaning power. The high-density weave with microfibers allows for the effective removal of contaminants. They are also available in a roll format for automated LCD manufacturing equipment.

Specialty Wiper

Wetted Wiper

Pre-saturated with a measured amount of chemicals, these wipers prevent potential accidents from bringing large volumes of chemicals into the cleanroom and avoid excessive chemical use. Wetted wipers enhance safety and simplify processes. They can be made from either nonwoven or polyester material.

Eco Wiper

Designed to address the issue of fiber leaching when wetted wipers are stored long-term, which can cause non-volatile residue(NVR) and contamination, Eco Wipers contain encapsulated chemicals that are separated from the wiper, allowing the chemical to be absorbed into the wiper upon opening. KM holds a patent for Eco Wipers.

Sterilized Wiper

Used in pharmaceutical and biotech industries, which often operate in sterile cleanrooms. The wiper is initially washed in ultra-pure water to remove ions and bacteria, then sterilized with gamma radiation for safety. Sterilized wipers are available in both polyester and nonwoven materials, in dry or pre-wetted formats.

Surface Preparation Wiper

These wipers are used for painting, coating, or adhesive applications that require a clean surface. They are commonly used in industries like automotive and aerospace rather than high-cleanliness cleanrooms.

For effective cleanroom maintenance, it is also important to clean floors, walls, and ceiling panels, which are frequently affected by personnel movement and environmental factors. Mops, vacuums, and swabs are essential for comprehensive cleaning.

Mop

Used to remove contaminants from floors, walls, and ceilings. Depending on the application, mops may be made from PVA pulp, nonwoven fabric, cotton, or sterile cloth. PVA pulp is suitable for wet cleaning, nonwoven fabric attracts particles with static, and sterile cloth is ideal for cleaning sterile room surfaces.

Swab

Swabs have tips made of 100% urethane foam or polyester and are excellent for cleaning small spaces, such as motor bearings or HDD heads, where contamination may accumulate in equipment crevices.

Vacuum

Equipped with multi-stage HEPA or ULPA filters, these cleanroom vacuums effectively filter particles as small as 0.3μm and are used to clean cleanroom surfaces.

Q.9

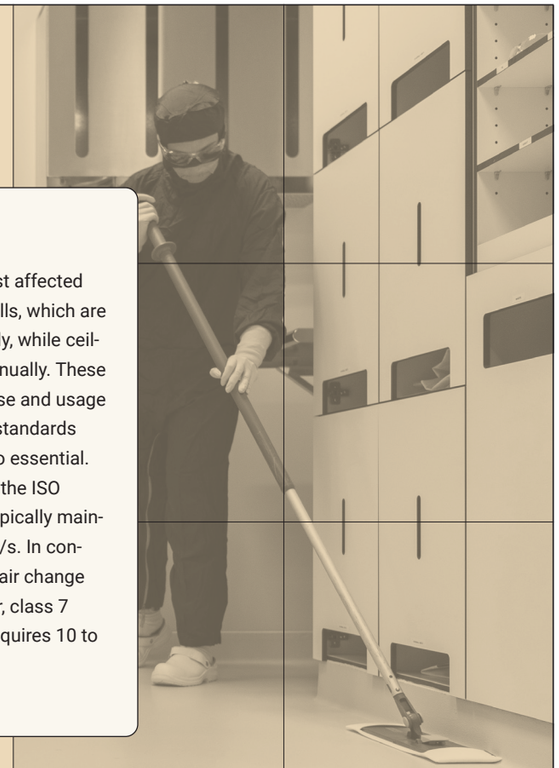
<KM Cleanroom Wiper Lineup>

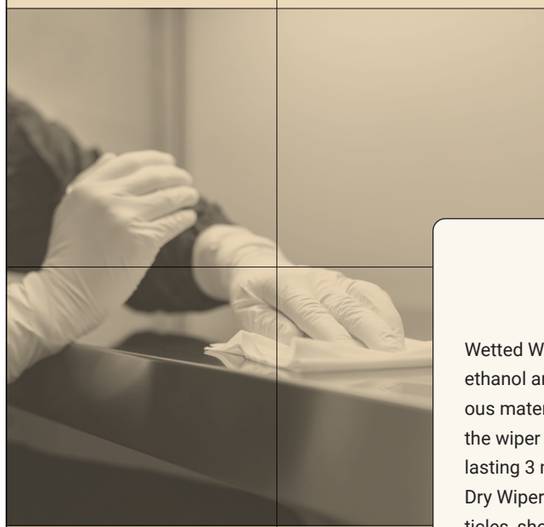
	Nonwoven Wiper	Polyester Wiper	Micro-denier Wiper	Eco Wiper
Material	Polyester+Cellulose Polypropylene	Polyester	Polyester+Nylon Polyester	Polyester+Nylon Polyester
Fabric	Nonwoven	Knit Woven	Knit Woven	Knit Woven
Type	Dry Pre-wetted	Dry Pre-wetted	Dry Pre-wetted	Dry to Wet
Size	6" × 6" 9" × 9" 12" × 12"	4" × 4" 6" × 6" 9" × 9" 12" × 12" 18" × 18"	6" × 6" 8" × 8" 9" × 9"	8" × 8"
Edge Type	Knife-cut	Sealed Edge Sealed Border	Sealed Edge Sealed Border	Sealed Border
Used With	Ethanol with DIW IPA with DIW	DIW Ethanol IPA	DIW Ethanol IPA	Ethanol Acetone
Sector	Semiconductors Electronics Pharmaceutical Healthcare	Semiconductors Electronics Pharmaceutical Healthcare	Semiconductors Electronics Opticals Automotives	Semiconductors Electronics
Suitable Class	ISO 5+ Class 100+	ISO 4+ Class 10+	ISO 4+ Class 10+	ISO 4+ Class 10+"
Availabe Sterile	◯	◯	◯	

Q.9 1

How often should a cleanroom be cleaned?

Floors, equipment, and work surfaces, which are most affected by personnel movement, should be cleaned daily. Walls, which are less frequently contacted, should be cleaned quarterly, while ceilings(in ISO Class 2 or higher) should be cleaned biannually. These guidelines may vary based on the cleanroom's purpose and usage frequency, and companies should establish custom standards through a risk assessment. Regular ventilation is also essential. In microelectronics cleanroom examples outlined by the ISO 14644 standard, ISO cleanliness classes 2 to 5 are typically maintained with an average airflow velocity of 0.2 to 0.5m/s. In contrast, ISO cleanliness classes 6 to 8 are regulated by air change rates: class 6 requires 70 to 160 air changes per hour, class 7 requires 30 to 70 air changes per hour, and class 8 requires 10 to 20 air changes per hour.





Q.9 2

Are there specific storage requirements and expiration dates for wipers?

Wetted Wipers and Eco Wipers contain hazardous chemicals like ethanol and must be stored in designated areas(such as hazardous material storage). The recommended shelf life depends on the wiper material and chemicals, with Wetted Wipers typically lasting 3 months and Eco Wipers 6 months.
Dry Wipers, which are washed in ultra-pure water to control particles, should be used immediately upon opening in a cleanroom to prevent contamination. When sealed, they can be stored in standard conditions, with KM recommending a shelf life of up to 2 years for Dry Wipers based on internal validation.

Q.10

What tests are required for ISO 14644 certification of a cleanroom?

The ISO 14644 certification, an internationally recognized standard, assesses a cleanroom's ability to maintain specific levels of airborne particles. Required tests include evaluations of particle concentration, airflow and air velocity, pressure differentials, temperature, and humidity.

Cleanroom equipment and systems must be planned according to domestic and international cleanroom standards, maintaining ISO 14644 certification with regular recertification to ensure cleanliness. Certification confirms that the cleanroom rigorously monitors the levels of organisms and contaminants present, providing a foundation for high-quality production and customer trust. Internationally recognized ISO 14644 certification involves the following 11 tests: KM

Air Differential Pressure Test
Verifies the performance of the air system to maintain a specified pressure differential between the cleanroom and surrounding environments.

Airflow Volume/Velocity Test
Measures the airflow volume for either unidirectional and non-unidirectional cleanrooms or clean zones.

Recovery Test
Determines if the cleanroom or clean zone can return to a specified cleanliness level within a set time after brief exposure to a source of airborne particles.

Q.10

Temperature Test
Ensures that the air temperature in the test area remains within control limits during a specified period as defined by the user.

Humidity Test
Verifies that humidity levels(expressed as relative humidity or dew point) in the test area stay within control limits over a specified period.

Leak Test for Filtered Systems
Confirms that there are no bypass leaks in the air filtration system, ensuring the final high-efficiency air filter system is properly installed and defect-free.

Particle Count Test
Measures the quantity and size of airborne particles in the cleanroom over a specified period. KM

Q.10 1

What certifications does KM hold?

KM holds ISO 14644 cleanroom certification, as well as certifications for ISO 9001, 14001, 45001, 13485, IATF 16949, Kosha product safety, and GRS.

Quality Management System(ISO 9001)
An international standard defining quality management system requirements for all industries and activities, providing third-party certification to verify that a company's product or service system meets specified requirements.

Recycled Fiber Certification(GRS) | A certification standard verifying the use of recycled materials in textiles and garment production. Applicable to products containing at least 20% recycled material.

Occupational Health and Safety Management System(ISO 45001) | A self-managed safety and health system that incorporates occupational health and safety policies into business management, defining detailed operational guidelines and standards. Organizations periodically assess and improve their safety and health plans.

Environmental Management System (ISO 14001)
A system for systematically managing environmental impacts across all organizational activities, products, and services within a company's production processes, services, and various operations.

Q.10 2

Information about Global Certification Organizations.

TÜV SÜD | TÜV SÜD, a global certification authority based in Germany, brings 150 years of expertise to support certification needs in the semiconductor, pharmaceutical, healthcare, and electronics industries. From ISO 14644 cleanroom certification to ensuring safety compliance across diverse sectors, TÜV SÜD helps create secure and reliable environments.
www.tuvsud.com

IEST | The Institute of Environmental Sciences and Technology(IEST), based in the United States, is a leading international organization specializing in cleanrooms, controlled environments, and industrial safety. Founded in 1956, IEST offers comprehensive guidelines on cleanroom design, operation, certification, and standardization while driving advancements in environmental science and technology across a wide range of industries.
www.iest.org

BSI Group | The BSI Group, a global standardization organization headquartered in the United Kingdom, offers quality and safety certification services, including ISO 14644 cleanroom certification. With expertise in industries such as pharmaceuticals, life sciences, and electronics, BSI helps businesses meet international standards through tailored cleanroom assessments and certifications.
www.bsigroup.com

SGS | SGS, a Swiss certification body with over 140 years of expertise, specializes in industries where cleanroom operations are essential, such as pharmaceuticals and healthcare. The organization offers ISO 14644 cleanroom certification to validate operational standards and provides monitoring services to ensure continuous compliance.
www.sgs.com

TECHNOLOGY TO ACHIEVE ZERO CONTAMINATION

10 Essential Questions About Cleanrooms

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10 ESSENTIAL QUESTIONS ABOUT CLEANROOMS

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