

# SPECTRUM

THE IE GROUP MAGAZINE

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## Hygiene and Cleanroom

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Technically, there are many ways to meet hygiene and cleanliness requirements. But are the solutions also efficient? IE shows how product safety and cost-effectiveness go hand in hand.



The specialist for industrial buildings.



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A CLEAN BUSINESS:

## Product safety, processes, and buildings in harmony

“There was no other way; our factory has grown organically.” We hear this a lot at IE when we visit production facilities with company decision-makers. In most cases, market pressure is so strong that management can only consider minor and as short as possible interventions when it comes to production conversions or expansions.

After many years, the result of these small, isolated measures usually looks like this: production steps in the wrong hygiene zones, raw materials and products being transported through the production facilities via convoluted routes, countless intermediate storage areas, uncontrollable personnel flows, missing or unnecessary airlocks. These consequences of uncoordinated individual solutions not only reduce efficiency. They also indirectly influence product quality and thus often also reject rates.

There is only one way out of this impasse: all existing and future processes in the company must be reviewed. Only on this basis can interactions be assessed and efficient processes defined and implemented. This holistic approach requires looking beyond the production facilities alone. Room furnishings, room layouts, and overarching location concepts are just as relevant. This applies to production facilities with low hygiene requirements as well as to clean rooms. Otherwise, lazy compromises will arise that will continue to proliferate over the years. Ultimately, they will jeopardize the company's profitability and product safety.

Whether it's a new building or an extension, your products and manufacturing processes are at the heart of the planning process. We would be delighted to implement this for you. You can rely on our production planners, cleanroom experts, architects, and specialist engineers. Together, they keep their eye on the big picture: the efficiency of your production and product safety.

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# THE SPATIAL ENGINE



# Those who understand the hygiene and cleanroom concept as part of the manufacturing process pave the way for high product safety and economical operation.

*The more critical hygiene and cleanliness requirements are for a company, the greater their importance for factory and building design. However, one thing is easily overlooked: product safety depends not only on individual measures and technologies, but also on the optimal interaction between processes, space, and technology. This applies even more to the economic efficiency of the business. A plea for interdisciplinary planning and a view of the bigger picture.*

“Our customer's existing cleanroom is far too large,” says cleanroom expert Stephan Fischer. “My initial capacity assessment shows that half the space would be sufficient if we optimally arrange and connect the two cleanrooms. This would significantly reduce operating and investment costs, and we would also have more space for the future packaging line.” Logistics expert Thomas Hanhart pipes up: “But we need a buffer, otherwise even a minor disruption will bring the entire material flow to a standstill. Unless we also relocate the picking area for goods delivery.” The civil engineer interjects: “Then we would have to reinforce the goods delivery area structurally. We would have to recalculate that – but it is certainly possible.”

## **All experts around one table**

IE planning-meetings always involve intense discussions. No wonder: industrial construction projects are extremely complex. A seemingly small change in one area can have a major impact on the entire building. “Before discussing possible solutions, the requirements for the space must be laid out on the table,” says Stephan Fischer, Product Manager for Hygiene and Cleanrooms. “This ensures that the process and the space ultimately form a unified whole.”

That is why IE brings together a wide range of experts right from the early stages of a project. Only through intensive exchange between all disciplines can solutions be developed that are convincing from every perspective. Our clients' employees play a very special role in finding solutions. It is important to us that the expertise of all key individuals is taken into account.

To manage complexity, IE follows a proven methodology: starting with the product and process, IE consistently plans from the inside out.

For many companies, the importance of hygiene concepts and clean rooms has increased in recent years: new technologies enable products of unprecedented quality and precision. Food companies are pushing their way onto the

⇒ *„The planning and construction of industrial buildings with hygiene requirements is highly complex. It requires networked thinking and a clear methodology.“*

Ernst Näf, Architect

⇒ *„The highest possible level of cleanness is not expedient, and certainly not economical. We do not strive for what is possible, but for what is expedient. Our hygiene concepts are based on what is necessary for the manufacturing process and compliance - not on what current cleanroom technology has to offer.“*

Stephan Fischer, Managing Director Life Science Zurich

market with minimum shelf lives that seemed unimaginable until recently. Comprehensive product and personal protection are required for pharmaceuticals and medical devices, not least because of strict regulatory requirements. At the same time, the cost of hygiene is increasing its impact on the profitability of operations. Half-finished solutions make production more expensive and jeopardize both product safety and economic success.

#### **Complexity: A threat to security and cost-effectiveness**

“Companies with high hygiene requirements in particular need to keep an eye on the bigger picture,” says Thomas Rieger, Managing Director of IE Technology. “It’s no use having a technically flawless clean room if it isn’t optimally integrated into the upstream and downstream processes.” IE specialists see time and again that interfaces are one of the biggest challenges.

When fundamental weaknesses arise, they often have to be compensated for with labor-intensive measures - day after day, during ongoing operations. Companies pay a high price for this in the form of inefficient employees, increased cleaning costs, and additional steps - to name just a few. Stephan Fischer, Managing Director for Life Science: “Anyone who is serious about high cost-effectiveness and product safety must keep production systems as simple as possible. High complexity and many dependencies



are very expensive to operate and can only be managed with great effort. It takes a lot more brainpower to set up processes that are as lean and logical as possible.”

#### **The product defines the process**

The maxim for IE is: The focus is on the product and the actual manufacturing process – not on individual machines or the available technology. Planners and suppliers who fail to properly understand this fundamental core of the business and think in terms of individual components can only produce patchwork solutions. That is why IE first works with the customer to examine the manufacturing processes and the relevant support processes. On this basis, the project teams develop the hygiene concept and determine the necessary building technology.

#### **Understanding the room as a machine**

It is obvious that companies with high hygiene requirements need industrial buildings that are tailored entirely to their manufacturing processes and hygiene needs: the higher the hygiene requirements, the more the room itself becomes part of the production facility. “In our planning, hygiene and clean room concepts are risk-based and exclusively a means to an end,” explains Stephan Fischer.

#### **Turnkey hygiene from IE**

With its interdisciplinary approach to hygiene and cleanliness, IE stands out from traditional service providers in this field. “Many companies find it difficult at first to classify our comprehensive services. Manufacturers of ready-made solutions, architectural firms, and engineering service providers often compete for the same contracts,” says Percy Limacher, Managing Director of IE Plast. “But after the kick-off meeting at the latest, companies realize



the advantages of IE not providing run-of-the-mill, off-the-shelf solutions, but rather industrial buildings that are tailored entirely to their individual requirements. Especially since we also offer guarantees for our services.” The proportion of returning customers speaks for itself: around 70 percent of IE's orders come from long-standing partners.



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## Industry expertise meets hygiene and cleanroom know-how

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Hygiene zones and cleanrooms can only be as good as their integration into upstream and downstream processes. That is why we at IE employ specialist engineers who are just as familiar with manufacturing processes as they are with the typical hygiene and cleanroom issues faced

by individual industries. Whether in high-tech, pharmaceuticals and biotechnology, medical devices, or the food industry, at IE you will meet experts who quickly grasp your situation and propose solutions that will help you move forward.

## HIGHTECH-INDUSTRY

# Appropriate cleanness instead of technological arms race

*For many years, the semiconductor and pharmaceutical industries have set the standard for dust- and particle-reduced processes.*

*However, for many high-precision manufacturing techniques, these purity requirements are far too demanding, and the sources of contamination are also completely different. IE plans and implements clean rooms and clean areas for high-tech companies that are tailored to the respective products and processes.*

### **Increasing demands**

New and more powerful assemblies require increasingly complex manufacturing methods. The demands on the process and the production environment are growing particularly rapidly in the fields of hydraulic and mechanical systems, optical components, and electrical engineering. The problems range from clogged nozzles and abrasion to stray currents and are as diverse as the processes themselves. The consequences are malfunctions, downtime of entire production lines, and high scrap rates. Ultimately, component cleanness is a quality factor and therefore also a question of economic efficiency.

⇒ *„In many cases, implementing a zone concept is more effective than installing oversized and maintenance-intensive ventilation systems. This allows processes that influence each other to be consistently separated spatially.“*

Thomas Rieger, Managing Director IE Technology Zurich

### **Holistic, process-oriented protection concept**

If, for example, printed circuit boards are used that can be short-circuited by metallic particles, all measures must be geared towards this – non-conductive dusts or textile fibers are less relevant.

In high-tech processes, the particle count is often just one criterion among many. High-precision temperature and humidity control, ionization, or ESD can be just as crucial to the process. Depending on the required criteria, the premises and building services must be adapted to the production processes.

## PHARMA AND BIOTECHNOLOGY

# Compliance and cost-effectiveness in harmony

*Hardly any other industry invests as much in product safety as the pharmaceutical and biotech industry. Everyday production is heavily influenced by in-process controls, endless batch records, numerous changing processes, and dozens of visas. But is the high cost of compliance always a good investment? With holistic and forward-looking planning, unproductive activities can be reduced - and product safety increased.*



### **Inadequate planning leads to high fixed costs**

The close interdependencies between cleanrooms and manufacturing processes often make it very costly to adapt processes once they have been implemented. Revalidations or even changes to registration documents are often necessary, as well as adjustments and SOPs

training. As a result, changes that make sense from an operational perspective are often not implemented, and high fixed costs remain.

This makes it all the more important to run through possible expansion scenarios in the early stages of cleanroom and building planning. It is also extremely important to include upstream and downstream processes in the overall planning, especially intralogistics.

⇒ *„A cleanroom may be state-of-the-art in terms of technology, but its potential cannot be fully exploited if the interfaces and intralogistics are neglected.“*

Matthias Jacubasch, Managing Director Life Science Munich

### **Cleanroom: From foreign body to qualified space**

IE designs cleanrooms to be fully aligned with process flows - not only core processes, but also support processes, which tend to be more manual in nature. Ventilation technology and media supply in particular have gained in importance in recent years and are increasingly coming under the spotlight of auditors. IE has extensive experience and a wide-ranging network for ensuring GMP compliance in GMP-critical projects.

## Plastics, assembly and packaging process from a single source

*Many plastics processors have successfully established themselves in the medical device sector in recent years. Increasing regulatory requirements, a dynamic market, and pressure on margins necessitate continuous change. The key to success often no longer lies in plastics processing alone - the processes downstream of the actual manufacturing process are becoming a key success factor. With increasing complexity and automation, the design of the production environment is becoming more and more important.*

### **Injection molding and extrusion**

Injection molding and extrusion are the most commonly used methods for manufacturing plastic medical devices. Both processes enable high-volume production. In most cases, subsequent washing or cleaning processes are neither economical nor effective. Cleanroom technology offers optimal protection for both technologies.

For many plastics processors, injection molding is only the first stage in an entire process chain. The actual added value and differentiation is often created in the downstream finishing processes.

### **Assembly and packaging process**

The packaging and assembly of individual parts or components often involves manual work. However, the trend toward automation is unstoppable, especially in high-wage countries such as Switzerland and Germany. Whether human or machine: IE is the right partner for creating the right working environment in clean rooms and ensuring the success of complex investment projects in the plastics, assembly, and packaging sectors.



Photo: ARBURG

⇒ *„The trick is to combine economic conditions with operational requirements. This applies to detailed issues such as tool handling for injection molding systems or higher-level site development as a strategic management tool for the executive board.“*

Percy Limacher, Managing Director IE Plast Zurich

## Hygiene zones: tailored to the process and product

*Regulatory requirements for medical products are constantly increasing. This usually results in rising production costs. Is there a way out of this cost spiral? Product safety and cost-effectiveness do not have to be mutually exclusive. The key to this is process-oriented buildings. The goal: the production environment is completely tailored to the company's processes, yet still offers enough flexibility to respond to market developments.*



### **Product safety through a holistic approach**

Particular importance is attached to upstream and downstream processes, such as the provision of raw materials or the process of entering a clean room. The higher the cleanliness requirements, the greater the importance of support processes, whether cleaning controlled zones, monitoring, or In-Process Control (IPC).

### **Appropriate hygiene through different zones**

The considerable heterogeneity of medical products is evident from their classification. A look at the manufacturing processes makes this even clearer. It therefore stands to reason that there cannot be a uniform industry hygiene concept, but that each individual process must be considered separately. An overarching hygiene concept "clusters" the most diverse requirements into zones. The risk-based allocation of the individual process steps is of central importance here. Otherwise, either product safety or economic efficiency is at risk.

### **Interdisciplinary collaboration**

Even perfect installation of the cleanroom is only useful if the overall hygiene concept is right. That is why it is essential to bring together experts from the fields of process and construction right from the start of planning. Only then can an industrial building be created that meets regulatory requirements and in which all processes can be organized efficiently. IE has the relevant experts on board, including for the planning of GMP-critical projects.

⇒ *„In order to ensure both cost-effectiveness and product safety, it is necessary to take a holistic view of all relevant processes and their environment. Only those who understand the processes can design the cleanrooms accordingly.“*

Stephan Fischer, Geschäftsführer Life Science Zurich

## FOOD INDUSTRY

# Product safety through risk-based hygiene concepts

*Food safety requirements are also constantly increasing. In order to meet these ever-higher standards, comprehensive hygiene concepts are required that are geared towards the essential processes. This is the only way to combine product safety and economic efficiency.*



### **Individual risk analysis instead of off-the-shelf solutions**

The particularly wide variety of raw materials and processing methods in the food industry requires an individual approach: a risk-based and site-specific assessment is essential if a targeted concept is to be implemented. IE takes into account company-specific, national, and international standards (BRC, IFS, and ISO/FSSC 22000).

### **Coordinated plant and building concept**

Employees who spend most of their working hours cleaning are not particularly productive. Instead, the plant and building concepts should be coordinated in such a way that, for example, dirt from a plant is not disposed of via the floor into a drain, which then has to be cleaned regularly along with the floor. In the food industry, too, the trend is towards using as little water as possible for cleaning work in as targeted a manner as possible. This is because water is an essential prerequisite for microbiological growth – unfortunately, other nutrients are found on many materials in a production facility. These developments must be taken into account during the planning stage and reflected in a comprehensive hygiene concept.

### **Extending shelf life:**

#### **Cleanroom technology in the food industry?**

Cleanroom technology has been an integral component of filling systems for decades. However, this measure

alone is not always sufficient to maintain a consistently high level of hygiene - the basic prerequisite for significantly extending shelf life. From a microbiological perspective, closed production processes are better suited to producing and filling food products in a low-germ or sterile environment.

When open processing steps are unavoidable, cleanroom technology offers interesting possibilities – through selective solutions or even for entire zones. Regardless of whether cleanroom technology is required or not, IE is the right partner for advanced hygiene concepts.



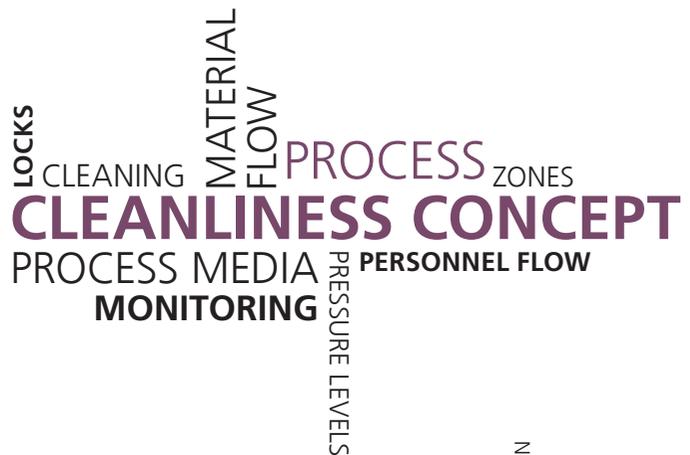
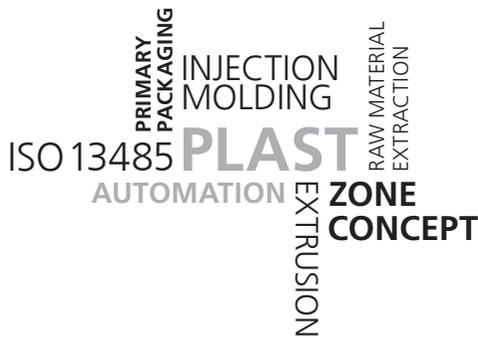
*„Our goal is not what is technically possible, but rather a suitable solution that is both effective and efficient.“*

Tobias Rosenbaum, Geschäftsführer IE Food München

# Our added value: Industry-specific process and factory planning

During your first meeting with IE, you will quickly realize that you are dealing with someone who not only understands your everyday concerns, but also finds new solutions tailored specifically to your situation. Not only are there experts in hygiene and clean rooms at the table, but also specialists in operations and construction

planning with industry experience. This allows us to quickly understand your workflows and production processes and implement the solutions we develop with you in terms of construction. The result: an industrial building that optimally supports your production processes and cleanliness requirements.






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## Our special services hygiene and cleanrooms

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### HYGIENE CONCEPTS

- ✓ Zone concepts
- ✓ Material and personnel flow
- ✓ Clothing and airlock concepts
- ✓ Disposal concepts

### CLEANROOM TECHNOLOGY

- ✓ Pressurization concepts
- ✓ Ventilation concepts
- ✓ Airflow concepts
- ✓ Energy-optimized ventilation systems
- ✓ Process media

### CLEANROOMS AND CLEAN AREAS

- ✓ Cleanroom concepts according to ISO/GMP
- ✓ Cleanrooms according to VDA
- ✓ Energy optimization in cleanrooms
- ✓ Cleanroom construction
- ✓ ATEX in cleanrooms
- ✓ Monitoring systems
- ✓ Cleanroom furnishings

### QUALITY MANAGEMENT

- ✓ Industry-specific planning
- ✓ Risk analysis
- ✓ Hygiene audit - operation and construction
- ✓ GMP-compliant qualifications: URS/FS/DQ/IQ/OQ

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### STRATEGIC PLANNING

- ✓ Site development / Master plan for hygiene zone
- ✓ Operating concepts
- ✓ Expandable hygiene areas
- ✓ Logistics concepts

### CONSTRUCTION PLANNING

- ✓ Sustainable construction planning for clean rooms, production, logistics, areas, laboratories, and administration
- ✓ New buildings
- ✓ Conversions
- ✓ Extensions

### BUILDING EXECUTION

- ✓ GMP-compliant Execution
- ✓ Construction during ongoing production
- ✓ Guarantees for costs, deadlines, function, quality

### PROJECT MANAGEMENT

- ✓ General planning
  - ✓ Overall coordination of plant construction, special media, and building planning
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Our specialists in the field of hygiene and clean rooms have one goal in mind: to combine high product safety with low operating costs. That's why we pay attention to even the smallest details without losing sight of the big picture. Our hygiene and clean room experts are involved

in the process from the planning stage right through to the completion of the industrial building. This enables us to create the ideal conditions for product safety – in an efficient operation.



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## Contacts

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