

 LIFE SCIENCE

The specialist for industrial buildings.



**PLASMIDFACTORY GMBH,
BIELEFELD**

INSIGHT



PlasmidFactory GmbH, headquartered in Bielefeld, is one of the world's leading contract development and manufacturing organizations (CDMOs) for plasmid and minicircle DNA. These products are used in particular in the development and manufacture of cell and gene therapies (e.g. CAR-T), for the production of viral vectors (e.g. AAV and LVV), as well as for vaccines (e.g. as starting material for mRNA production). Since its founding in 2000, PlasmidFactory has grown continuously and has steadily expanded its capacities. Following the commissioning of laboratories for DNA in High Quality Grade (in accordance with EMA guidelines), the company decided to realize a fully GMP-compliant production facility by constructing a new laboratory building. IE Life Science was commissioned with the planning.

PlasmidFactory's plasmid and high-performance minicircle DNA have seen steadily growing demand worldwide, particularly in research as well as in the development of cell and gene therapies and other biopharmaceutical applications. A team of highly qualified scientists and specialists from the fields of biology, chemistry and engineering develops products according to customer specifications in various quality grades and is able to provide them in scalable quantities. The company's core business comprises customized DNA solutions, complemented by services such as analytics and DNA storage. To date, PlasmidFactory has been able to produce plasmid and minicircle DNA up to High Quality Grade. As part of its growth strategy, the company's management decided to build a GMP-compliant facility in order to initiate the production of DNA for clinical applications through to commercialization. For the planning of the new building on the site of the Bielefeld Technology Center, PlasmidFactory commissioned IE Life Science, which planned and implemented the project as a general contractor.

CLEANROOM LABORATORIES – ELITE CLASS OF INDUSTRIAL CONSTRUCTION

NEW GMP-LABORATORY FOR PLASMIDFACTORY GMBH



«Establishing a GMP-compliant infrastructure is a key step in ensuring that future requirements in cell and gene therapy as well as in clinical development can be met reliably.»

*Dr. Dirk Winnemöller,
CEO PlasmidFactory GmbH*



SUCCESS FACTORS

1

IN-DEPTH UNDERSTANDING OF HYGIENE-SENSITIVE LABORATORY AREAS

HOLISTIC PLANNING DRIVEN BY PROCESSES.

For planners at IE Life Science, the primary focus is not on building design. Instead, they begin with operational processes, from which the architectural appearance is ultimately derived. This approach was also applied to the new GMP laboratory project for PlasmidFactory. In close collaboration with the client's scientists and process engineers, IE Life Science defined the required cleanroom capacity volume and cleanroom classes during the planning phase. On this basis, IE planners developed an operational layout and an intelligent zoning concept, taking into account the specific conditions in biotechnological production facilities.

Following the successful completion of preliminary planning and the granting of the building permit, IE Life Science was also commissioned as general contractor to carry out detailed design and implementation of the GMP project.

2

INTEGRATED PLANNING BASED ON A HOLISTIC APPROACH

PERFECT INTERPLAY OF DISCIPLINES.

For this construction project, which is characterized by cleanroom production, IE Life Science pursued an integrated planning approach. During detailed design, the architects and structural engineers from IE worked closely from the outset with specialist planners such as cleanroom experts, process engineers, HVAC engineers, electrical engineers, and other trades. The multidisciplinary collaboration under the leadership and coordination of IE Life Science ensured that the cleanrooms met all functional requirements in accordance with applicable standards and the targeted GMP standards.

The qualification of the cleanrooms was also carried out by IE. In doing so, IE's experts consistently kept GMP-relevant aspects in focus. In weekly meetings between planning experts, specialists and the client, current issues were clarified and the approach for process design as well as the integration of technical systems was coordinated among all parties involved.

3

MODULAR CONSTRUCTION CONCEPT FOR CLEANROOMS

PROVISION OF PRODUCTION RESOURCES.

Modular construction is increasingly being adopted in laboratory construction. It accelerates the availability of production resources, reduces costs, and allows structures to be adapted to new requirements when necessary. The planning for the PlasmidFactory laboratory building included a total of 16 modular cells. These were arranged on the ground floor into a total of 4 cleanrooms in cleanroom classes C and D in accordance with the developed zoning concept. On the upper floor, the necessary building services systems were installed, along with rooms for additional technical purposes. The gross floor area amounts to 580 m².

While construction partners, in accordance with IE Life Science's design, prepared the foundation for the new building and the building envelope, the cleanroom cells were prefabricated and designed from the outset for GMP fit-out. The technical installations (HVAC, sanitary and electrical systems) were implemented in coordination with the planning and realization of the cleanrooms.

A notable special feature is the implementation of continuous "single-use processes" along the upstream and downstream processing chain.

4

CLEANROOM PLANNING WITH COMPREHENSIVE GMP KNOW-HOW

ENSURING PRODUCT SAFETY AND GUARANTEED QUALITY.

IE has been planning and building industrial buildings for the production of hygiene-sensitive products for more than 50 years, with a focus on biotechnology, pharmaceuticals and medical technology. The planning and execution of the new building for PlasmidFactory provided IE planners with the opportunity to demonstrate their expertise in GMP-compliant production facilities within a modular construction concept. Secure airlock systems, optimized material and personnel flow, and a well-designed ventilation concept ensure strict compliance with GMP standards. Particular attention was paid by the planners to the issue of cross-contamination, which poses an acute risk especially in laboratory operations.

Quality control was also given high priority during the planning phase: all relevant areas, procedures and processes are embedded in a clearly structured GMP quality management system that takes into account the different quality levels of products demanded by the market.

5

IE LIFE SCIENCE AS A GENERAL CONTRACTOR

PROJECT IMPLEMENTATION IN CLOSE COORDINATION WITH THE CLIENT.

As general contractor, IE Life Science coordinated the planning partners and trades involved. After completion of the new building, the client was able to take over the cleanrooms and start production in accordance with GMP standards. The production building, with its functional architecture tailored to production processes, integrates harmoniously into the PlasmidFactory site in Bielefeld. The new building represents an important milestone for the company's strategic direction and innovative strength.

IE Life Science supported the project in its role as general contractor and thus enabled the successful implementation of the new construction.



PERFORMED BY IE LIFE SCIENCE

- › Project management as general contractor
- › Feasibility study, concept study, construction project, tenders and construction execution



IE LIFE SCIENCE

The specialist for industrial buildings.

We are the IE Group: Your specialist for industrial buildings.

We plan, design, and construct industrial buildings. Our goal is to maximize the efficiency of your production - with the help of industrial buildings that are perfectly tailored to your manufacturing processes. We work in manageable and therefore effective teams of industry experts whose motivation and initiative you can rely on. Because at our company, all employees are involved in the business. It goes without saying that we also give you guarantees on costs, deadlines, and quality. **IE Plast, IE Food, IE Life Science** and **IE Technology** are part of the IE Group, which has been on the market since 1966 and offers the necessary financial backing - even for large construction projects.



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SECURITY THROUGH GUARANTEES

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