

# Dealing with Regulatory Requirements and Public Authorities

Saving time and money by concentrating on core businesses

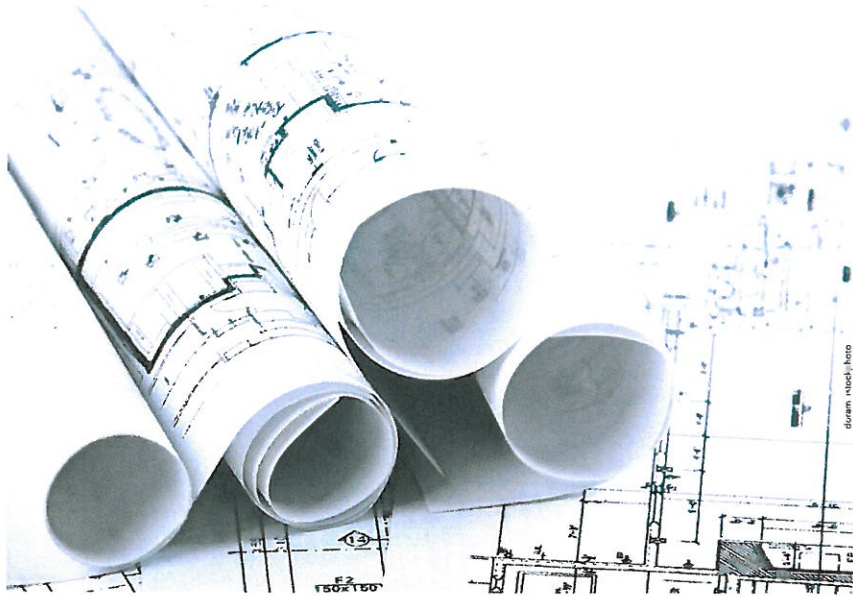


*Newly-settling chemical, Pharma or biotech companies face more or less the same challenges in building a new location: regardless of whether they are start-ups on their way to initial settlement, new subsidiaries of foreign enterprises or local companies planning to extend their facilities, they must deal with regulatory requirements and with public authorities monitoring their implementation. Additionally, regulatory affairs such as planning and building laws, operational approval or safety regulation are usually not the core business of a chemical, pharmaceutical or biotechnological company. In many cases, a site operator is able to cover those duties as a service. However, also external contractors might be worth a thought.*

BEOS as the owner of the industrial park Campus Oberhafen provides commercial real estate and project management in developing locations throughout Central Europe. The case of the laboratory and industrial park Campus Oberhafen differs from other projects, since laboratory sites and small chemical, pharmaceutical or biotechnological production require special know-how in dealing with the different regulatory requirements and public authorities involved. BEOS therefore relies on the services of the local facility management company GIG international facility management GmbH (GIG).

## **A triple-win situation**

At Campus Oberhafen and on behalf of BEOS, GIG operates daily business such as security services and catering and carries out duties involving repairs, refurbishing and the like. Furthermore, the facility service provider acts as operator of laboratory area and administers GMP-conform production as well as the stocks of hazardous materials. Operations are the strong suit of GIG, especially with sophisticated, interdisciplinary processes. GIG provides solutions for special customer needs that require many different services. As the third group of participants, public authorities benefit from a central contact within the regulatory and monitoring processes.



### Projects and services realised

One of the German subsidiaries of Aeterna Zentaris, a global biopharmaceutical company, is located at Campus Oberhafen. Being one of the leading companies in drug discovery, GMP compliance is essential for the company's success. With its subsidiary GIS Infraside, GIG provides and maintains cleanroom technology and reception and dispatch of hazardous goods as well as special waste management. Additional mandates cover equipment inspection and testing as well as warranty tracking for engineering services.

In the case of resettlement of Morphisto GmbH to Campus Oberhafen, GIG successfully provided help in any applicable issues of water pollution and emission control as well as maintenance of industrial health and safety standards. At a certain point of progression of the settlement negotiations, specifications of regulatory requirements were discussed with the customer and the necessary approvals for company operations were fixed in a roadmap. These subsequently were obtained. In cooperation with external partners and local authorities, GIG thereby prepared risk assessment as well as explosion prevention documents. Currently GIG supports Morphisto GmbH in obtainment of quality management certifications according to DIN-ISO 9001 and CE.

### Contact



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