

RCPE

Research Center Pharmaceutical Engineering GmbH

Programme: COMET – Competence Centers for Excellent Technologies

Programme line: K1-Centres

RCPE opens unique Pilot Plant

The research company RCPE GmbH, headquartered in Graz, has invested more than five million Euros into its new Pilot Plant. This unique facility will accelerate the development process of innovative pharmaceuticals from different areas such as personalized medicine, ensuring an expedited market launch. Bridging the gap from laboratory to commercial manufacturing poses serious challenges to long-term billion Euros development projects.

The journey from the discovery of new pharmaceutical agents towards the development of production-ready drugs can be long and tedious. About twelve years and two billion Euros are invested into any pharmaceutical drug that is introduced to the market. However, these demanding efforts pay off. New and tested drugs provide patients with more efficient and better options for treatment or at times can literally be their only life saver. The extensive research and the continuous development of more effective methods of treatment are of the utmost importance for the health care system.

RCPE's new Pilot Plant in Graz offers the opportunity to decrease the length of the development processes, not only saving development costs but enabling a quicker market launch and ultimately earlier availability for patients.

Immediate tests with highly potent agents

“Due to our high security level, we can now work with highly active substances such as hormones, eliminating one intermediate step in the development process”, explains Johannes Khinast, Scientific Director of RCPE. Until now, promising concepts or developments had to be tested and verified with placebos first, often delaying industrial implementation. Secure environments are essential for working with

highly potent agents which are potentially toxic. The Pilot Plant in Graz is the first research facility worldwide where manufacturing processes until hazard class OEB4 (Occupational Exposure Band describes the air pollution with dangerous materials at the workplace within the classes 1-5, similar to the fine particle pollution in clean rooms) can be tested. Furthermore, the facility is also equipped to work with explosive materials.



Fig. 1: The new Pilot Plant (Copyright RCPE)

Impact and effects

Pharmaceutical research is in constant transition. New, highly effective drugs as well as forms of administration and application are extensively

researched. Particularly within “personalized medicine”, the utilization of fewer but more potent substances is striking. However, these agents require special and often specific security measures. An essential part of development processes are production tests. While new ingredient combinations can seem promising in the laboratory, commercial manufacturing poses different challenges and difficulties, often rendering previously working processes and methods useless. With the new Pilot Plant, pharmaceutical drugs can be developed and tested under near serial production conditions almost simultaneously.

to two years”, states Thomas Klein, Business Director of the RCPE, “this is attractive for new and existing customers.” Even before officially opening, half of the capacity has already been designated to specific research projects for a variety of customers until 2020. After one year of planning and construction, the pilot plant is now fully ready to operate which includes 20 additional staff members. To comply with strict security requirements, any work will be conducted in low pressure environments. Additionally, a special ventilating system guarantees that the air is exchanged 30 times per hour, ensuring the utmost safety of the employees.



Fig. 2: The clean room for highly potent pharmaceutical agents (Copyright RCPE)

This globally unique infrastructure for independent research renders the biotech and pharmaceutical research area Graz and Styria more appealing to national and international pharmaceutical companies. In consequence, Austria has been strengthened and reinforced as an internationally competitive research location for pharmaceuticals. The proprietors of RCPE consider the K1-Center to be able to deliver research on the highest level, connecting science and industry to the benefit of both.

“As procedures and techniques can be tested with the agents, the market introduction process of pharmaceutical drugs can be reduced by one

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