

COMPANY PROFILE

GMP expert with new strategy

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► Since the middle of 2007, Gedeon Richter Plc. (Budapest) a leading pharmaceutical firm in Eastern Europe with branches in more than 100 countries, and Hamburg-based HELM AG, one of the largest independent chemical and pharmaceutical marketing enterprises in the world, have used their earning power and expertise both as a guarantee for the favourable development of Richter-Helm BioLogics GmbH & Co. KG and Richter-Helm BioTec GmbH & Co. KG.

More than 20 years of experience in the fast-growing science of biotechnology, along with the innovative strength of high-performance teams coupled with the solid foundation of the owner companies Gedeon Richter Plc. and HELM AG provide the guarantee for a successful partnership.

GMP services

Richter-Helm BioLogics offers services for the development and manufacture of biopharmaceutical products from customers in the pharmaceutical and biotechnology industries. The company produces recombinant proteins, plasmid DNA and vaccines in microbial systems. Richter-Helm BioTec is responsible for business development, marketing & sales activities and the management of product developments, not only for their own pipeline but also for joint venture development work in collaboration with associate companies. In order to enlarge the product pipeline, Richter-Helm BioTec is actively seeking further development projects at all stages, and can be viewed as the often missing link between biotech companies and the pharmaceutical industry. Its world wide presence allows the company to fully exploit



the market potential of products on a global basis.

Due to long standing experience with protein expression systems, plasmid DNA technologies, downstream processes and cGMP manufacturing, the firm is in a position to offer a first-class service to customers, from the development through to the production stage. Our development services comprise the establishment of production strains as well as the development of fermentation and downstream processes for manufacturing of recombinant proteins and plasmid DNA. In

our state-of-the-art cGMP production facilities we set up cell banks (MCB and WCB) and produce biopharmaceuticals, both for clinical trials and market supplies.

Broad expertise

Richter-Helm BioLogics and Richter-Helm BioTec currently employ about 100 specialists organised in interdisciplinary teams at 3 different working sites. Our Hamburg branch specialises in process development and analytical development, including development of bioassays. This plant also has a cGMP-accredited quality control laboratory. Our Hanover and Bovenau-based facilities manufacture and test biopharmaceuticals in accordance with the principles of Good Manufacturing Practice (GMP code). With the facility in Bovenau, Richter-Helm operates one of the most modern biotechnology facilities in Europe. This 4,500 m²-production plant near Hamburg was designed as a multipurpose facility for GMP-compliant manufacturing of recombinant proteins, plasmid DNA and microbial vaccines that meets FDA and EMEA requirements. Starting with the lay-out of the facility, Richter-Helm placed emphasis on preventing cross-contamination and mix-ups. Biological and non-biological areas are strictly separated. The different clean room areas can only be entered through dedicated airlocks, and each production area has dedicated staff. Additionally, 7 independent ventilation systems in the different production areas prevent cross-contamination. Main production equipment is cleaned in place (CIP) and steamed in place (SIP). Sterilisation is performed with pyrogene-free clean steam. All data from GMP relevant systems are recorded by a process management system. Richter-Helm performs full analytical services, including quality control of raw materials, environment, in-process samples and release testing.

Our versatile technological equipment enables us to respond to diverse customer requirements including different separation, lysis, refolding and purification protocols. Our goal is to provide customised solutions to our clients and partners. ◀