ABOUT US

Founded in 1996 in Budapest, Hungary by Dr. Géza Schneider, CF Pharma Ltd. is a privately owned, independent Hungarian developer and producer of active pharmaceutical ingredients (API).

We are specialized in the development and manufacturing of high-quality, complex APIs with proven experience in handling complex and hazardous chemistry. This allows CF Pharma to be a partner of choice in the development of difficult to make molecules. Our experienced R&D teams with strong skills in chemistry are developing new chemical processes and optimizing existing ones in our laboratories.

Our R&D and production plants based in Europe. We are regularly inspected by the Hungarian National Institute of Pharmacy and Nutrition.

OUR HISTORY

OUR COMMERCIAL PARTNER

Pátriapharma Ltd.

WORLDWIDE MORE THAN

30 countries

150 partners

Active API registrations by countries

Technologies

Technologies

CF Pharma has extensive knowledge and strong skills in chemistry and process development with proven experience in conducting complex, hazardous and nontrivial chemical synthesises, which allows CF Pharma to be a partner of choice in the development of "difficult to make" molecules.

After upscaling the production, CF Pharma is able to produce various APIs in bigger amounts, up to few hundred and thousand kilogram per year.

For the last stages of syntheses the reactors are used in Chemistry Plant I and Plant Chemistry II. All the manufacturing processes are finished in the designated Clean Area of Chemistry Plant I., which also includes drying, milling, weighing and packaging of the products.

Research and Development

Research and Development

The core elements of CF Pharma are excellent chemistry skills combined with long-term experience.

For more than 20 years Research and Development of APIs have played a key role in our strategy. In our three different R&D laboratories more than **25** API manufacturing processes have been developed for small and intermediate scale production. We commit substantial resources to sharpen or develop new technologies.

We know how to develop proprietary, non-infringing processes for the production of difficult to make API's, in order to offer our partners the optimal solution in terms of availability and timing.

In the area of complex, hard to develop generics our highly qualified and trained chemistry and pharmaceutical experts are capable of performing all the necessary development and scale-up and know-how exploitation. Researches aim to elaborate innovative manufacturing technologies for the production of generic APIs as well.

Our **R&D** teams are working on dozens of projects. If interested, we are ready to share cooperative opportunities with you.

Quality Management

The Quality department includes: **Quality Control, Quality Assurance and Regulatory Affairs units**. These separate units jointly ensure to meet the required quality and regulatory provisions of our Customers over the whole manufacturing process.

Based on the national legislation and the international GMP regulations – a thorough quality assurance system has been established and implemented in order to regulate all the quality sensitive methods and processes and to ensure the cooperation and support of the employees at all levels.

Among the greatest strengths of CF Pharma are Quality Assurance and Control and Regulatory compliance, which cannot be proven better than the Company's excellent performance on the regular inspections by the Hungarian National Institute of Pharmacy and Nutritiony.

Quality Control

Raw materials, intermediate products, active substances and packaging materials are all checked for compliance with specifications. In the pharmaceutical development phase, analytical methods are developed and validated, which includes the characterization of active substances and reference substances as well as stability testing of possible by-products and degradation products based on international guidelines.

Quality Assurance

- EU-GMP Certificate for 8 APIs
- Japanese Accreditation
- Regularly inspected by Hungarian National Institute of Pharmacy and Nutrition
- HALAL Certificate for 4 APIs

Quality management requires a robust system for the continuous quality improvement, quality assurance and the possibility of the integration of potential cost saving methods. Every deviation regarding the quality is thoroughly investigated by our team of highly skilled professionals in order to ensure the continuous high-quality performance and the undoubtable quality of our products.

The Management distinguishes between preventive and corrective actions, both of which are used in the quality control system in a transparent and open manner by all involved parties. Regular audits and inspections are performed in order to confirm compliance with all applicable customer and regulatory guidelines.

The close collaboration between Regulatory Affairs, Quality Control, Quality Assurance and Research and Development departments allows us to provide the Customers with the documentation required for the submission of registration applications.

We firmly believe that the close cooperation we maintain with our customers and sharing of our experience and different points of view enable us to challenge, maintain and improve our quality system.

Regulatory Affairs

Experienced, on-site Regulatory Affairs team ensures regulatory compliance by preparing and maintaining regulatory documentation such as Drug Master Files and CEPs. We provide strong regulatory performance with regulatory agencies around the world.

Get product brochure for more details