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ChemCon – A Successful Start-Up Story

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Abstract: ChemCon is a good example of the approximately 300 new companies founded in the BioValley over the past 15 years that are involved in the life sciences in one way or the other. ChemCon is engaged in contract research and custom synthesis of active pharmaceutical ingredients and intermediates. The products are manufactured on small scale under GMP-conditions. Based in Freiburg employing 40 people, ChemCon recently expanded into the USA.

Keywords: Active pharmaceutical ingredients · BioValley · ChemCon · Contract research · Custom synthesis · GMP-material

Today a company operating worldwide with four subsidiaries, specialized in producing GMP-material in injectable grade in FDA-approved clean-room facilities! How can you get there? The following track record shows how a simple idea can become reality.

The photograph shows the founders of ChemCon, Dr. Peter Gockel (right) and Dr. Raphael Vogler (left). In 1994 they started their first mutual research project at the Albert-Ludwigs University in Freiburg. This was also the beginning of an extraordinary friendship between the subsequent ChemCon founders and after a few months the first idea arose to start a business together. In January 1997 the business idea became more concrete. Both, students without money, had been aware of the immense costs of laboratory equipment. Therefore the plan was for a consulting company named 'Private Institute for **Chemical Consulting**'. After a few considerations and advice the company name '**ChemCon**' was born.

Started in May 1997 at Dr. Gockel's home in Schallstadt, it was a stony road until the young company could open their first CGMP clean-room facility in June 1998 in the Innovation Park in Freiburg. Since ChemCon worked under CGMP guidelines right from the beginning, it was soon necessary to extend the capacities with a microbiological department and an R&D laboratory in March 1999. With a professional biologist, ChemCon was able to perform the microbiological qualification of clean-room



Dr. Peter Gockel (right) and Dr. Raphael Vogler (left)

facilities, production control, and also microbiological release analytics of APIs (bioburden und endotoxin). Henceforth contract research and custom synthesis of active pharmaceutical ingredients (APIs) and intermediates on the small scale became the main focus of the company.

The next fundamental milestone was in July 2000 when ChemCon passed the first FDA audit with no deficiencies. With this the company was significantly involved in one of the fastest registrations of a cytostatic in the FDA's history. With a growing number of projects and employees ChemCon decided to establish their own analytical department in 2000. Today the slowly but continuously growing Analytical Department has a size that makes ChemCon nearly independent from analytical service suppliers. Measurements like NMR, HPLC, GC, IR, UV, polarity, ROI, potentiometric titrations, etc. can be performed in-house, which speeds up especially projects with a high R&D character with method development and validation. Since quality assurance is absolutely essential for ChemCon, the company's release analytic has an important status. Therefore all analytical equipment is qualified and has been through DQ-IQ-OQ-PQ.

The company's simple strategy 'growing with our projects' practiced by ChemCon founders Dr. Gockel and Dr. Vogler since ever, has led to a modern and innovative company with 40 employees and premises of about 2500 m² in Freiburg. Nevertheless the main focus of 'small scale and high quality' was always retained. In the large field of small molecular organic and inorganic APIs ChemCon is not limited to a special area of application. The great expertise of ChemCon's chemists assures a competent handling of almost all types of chemistry, which comprises the elaboration of the best synthetic routes and then of course a safe transfer from R&D to manufacturing under CGMP. Among the different APIs produced by ChemCon are substances for the treatment of a special type of childhood leukemia, hypertension, lung cancer or rheumatoid arthritis. Up to now ChemCon has handled more than 1000 projects, produced 250 different substances used for pre-clinical studies, all clinic phases up to past NDA. Five of ChemCon's active pharmaceutical ingredients are currently used for drugs on the American and European markets.

A special line that differentiates ChemCon from many other service companies is the extensive expertise in bioinorganic and metal-containing APIs, which can be traced back to the founders' doctoral theses.

In August 2003 the ChemCon America Inc. was founded in Florida. This well-planned step was made to intensify the services for U.S. customers. Today ChemCon America Inc. has an office in Lake Mary near Orlando and another in Detroit/Michigan. A local R&D laboratory will follow the sales and service offices in the near future. Now as before ChemCon is an independent and 100% privately held company, which has doubled turnover each year since 1998.

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